IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HUMANA INC.,

Plaintiff,

v.

INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS INC.; INDIVIOR SOLUTIONS INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS SOLUTIONS INC.; INDIVIOR PLC; RECKITT BENCKISER GROUP PLC; RECKITT BENCKISER HEALTHCARE (UK) LTD; and AQUESTIVE THERAPEUTICS, INC. f/k/a MONOSOL RX, LLC;

Defendants.

COMPLAINT

JURY TRIAL DEMANDED

Civil Action No.: 2:20-cv-04602

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COMPLAINT

Plaintiff Humana Inc. ("Humana" or "Plaintiff") hereby sues Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals Inc., Indivior Solutions Inc. f/k/a Reckitt Benckiser Pharmaceuticals Solutions, Inc., Indivior plc, Reckitt Benckiser Group plc, and Reckitt Benckiser Healthcare (UK) Ltd. (collectively, "Indivior") and Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC ("MonoSol") (together, "Defendants"). Based on personal knowledge as to facts pertaining to it, the investigation of counsel, and upon information and belief as to all other matters, Humana alleges as follows:

NATURE OF THE CASE

1. As our nation was being ravaged by the opioid crisis, there was one critical treatment for opioid addiction: Suboxone tablets. Suboxone is approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo treatment for opioid-use disorder. Introduced by Indivior Inc. (at the time, known as Reckitt Benckiser Pharmaceuticals Inc.) in 2002, Suboxone tablets quickly became a mainstay of opioid addiction treatment with annual United States sales of over $1 billion. Because the United States Food and Drug Administration ("FDA") designated Suboxone as an "orphan drug," it was sold by one company: Indivior.

2. By 2009, just as the opioid epidemic was spreading at an alarming rate throughout the United States, Indivior was facing its own impending crisis—its regulatory exclusivity for Suboxone tablets was about to expire. Generic pharmaceutical companies were waiting in the wings to launch less expensive versions of Indivior's crown jewel product, which would result in its price collapsing to pennies on the dollar. Indivior decided that it had to prevent that from happening. To do so, Indivior engaged in a complex, sophisticated scheme—including a pattern

of racketeering activity involving mail and wire fraud, deceptive, unfair, illegal, and criminal practices—to introduce a fraudulent new product in order to keep its Suboxone drug prices artificially high and unlawfully impede generic manufacturers from competing effectively.

3. It worked. Through these machinations, Indivior not only delayed generic entry, but also crippled the market for those products by creating a false narrative about a safety concern with its own tablet—a concern that the FDA ultimately dismissed as unsupported. Nonetheless, while the FDA fulfilled its duty to investigate this "concern," Indivior made and marketed a new form of Suboxone—a film. Through fear, coercion, and outright threats to pull Suboxone tablets from the market, Indivior successfully switched approximately 85% of patients to Suboxone film before competing manufacturers were authorized to sell generic versions of the tablet. Suboxone prices remained high as the opioid epidemic spiraled out of control. Indivior's profits soared, while doctors and clinics on the front line fought the rising tide of the opioid pandemic and Humana continued to pay higher prices for treatment of its insureds even though safe, effective, and cheaper alternatives were available.

4. This was no garden variety fraud scheme. The Suboxone fraudulent film scheme (referred to herein as the "Suboxone Scheme") resulted in the criminal indictment of Indivior for crimes, including mail and wire fraud by a federal grand jury on April 9, 2019.[1] That indictment, for the first time, revealed the shocking facts behind the Suboxone Scheme. In July 2019, Reckitt Benckiser Group plc, Indivior Inc.'s former parent company, paid $1.4 billion to resolve its potential criminal and civil liability related to a federal investigation of the marketing of Suboxone. This was in addition to the $50 million Reckitt Benckiser Group plc paid to settle an action brought by the Federal Trade Commission (the "FTC") alleging that Reckitt Benckiser

[1] Grand Jury Indictment of Indivior Inc. and Indivior plc, dated April 9, 2019, attached as Exhibit 1.

Group plc violated the antitrust laws through its efforts to thwart lower-priced generic competition to Suboxone. But despite these settlements and in the face of criminal charges, Indivior continued to hide the truth. It failed to correct its false and misleading statements made to health plans like Humana. To the contrary, on the very day the indictment was announced, in an open letter from the Indivior Chairman of the Board, Indivior rebuked the government for bringing criminal charges against the company. The Chairman explained that "[t]he Indivior Board of Directors, including through a special committee of the board that [he] chaired, [] investigated the department's allegations, and the board believes they are flat wrong."

5. But on August 14, 2019, the government filed a superseding indictment, revealing even more unsavory facts regarding the Suboxone Scheme.[2] In the following year, Indivior's Chief Executive Officer and Chief Medical Officer pleaded guilty to criminal informations filed against them and admitted to making false statements regarding the safety of Suboxone film.[3]

6. Less than a month after the Chief Executive Officer pleaded guilty, the other shoe dropped—on July 24, 2020, Indivior Solutions Inc. pleaded guilty and admitted that it, "knowingly and willingly made materially false statements . . . in connection with the delivery of and payment for health care benefits, items, and services,"[4] based on the very Suboxone Scheme at issue in this case. Indivior also admitted that "it failed to correct its inaccurate, false, and misleading statements made to"[5] a health plan.

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[2] Grand Jury Indictment of Indivior Inc. and Indivior plc, dated August 14, 2019, attached as Exhibit 2.
[3] Criminal Information of Shaun Thaxter, dated June 30, 2020, attached as Exhibit 3; Criminal Information of Timothy Baxter, dated August 31, 2020, attached as Exhibit 4.
[4] Criminal Information of Indivior Solutions Inc., dated July 24, 2020, at p. 8, ¶ 28, attached as Exhibit 5.
[5] *Id.* at p. 8, ¶27.

7. On that same date, Indivior entered into a civil settlement agreement with the United States Department of Justice ("DOJ") regarding allegations that it submitted false claims to federal and state government Medicare and Medicaid agencies in connection with the Suboxone Scheme. Indivior's $600 million settlement with the DOJ included an extraordinary requirement that Indivior completely disband its United States Suboxone sales force and never reinstate it. Indivior also entered into a $10 million civil settlement with the FTC, resolving claims that it engaged in illegal monopolization and anticompetitive conduct.

8. Indivior's profit-protection Suboxone Scheme made it billions of dollars — money paid out by patients, clinics, and health insurers, like Humana. Indeed, Indivior's Suboxone film product was itself a fraud. But for this criminal Suboxone Scheme, Indivior never would have introduced its fraudulent film product, and Humana never would have paid for a single packet of Suboxone film. Nor would have Humana, but for this criminal Scheme, have paid inflated prices for Suboxone tablets.

9. The facts revealed in the three criminal informations and two grand jury indictments are incorporated by reference.[6] The facts in those criminal informations and indictments and the facts described in this Complaint are essentially the same. The only real difference is that Humana is prosecuting these claims in an effort to recover sums it paid as a direct result of Indivior's Suboxone Scheme, as well as damages and attorneys' fees. Therefore, Humana has alleged additional relevant facts that demonstrate it was a victim of that very same Suboxone Scheme.

10. In executing the Suboxone Scheme, Indivior and MonoSol engaged in: Violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)

[6] Attached as Exhibits 1-5 and incorporated by reference.

(Count I, against all Indivior Defendants); Conspiracy to Violate the RICO Act, 18 U.S.C. § 1962(d) (Count II, against all Defendants); Fraud (Count III, against all Defendants); Monopolization (Count IV) and Attempted Monopolization (Count V) under various state laws (against all Indivior Defendants except Reckitt Benckiser Healthcare (UK) Ltd.); Unfair and Deceptive Trade Practices (Count VI, against all Defendants); Insurance Fraud under various state laws (Count VII, against all Defendants); and Unjust Enrichment (Count VIII, against all Defendants).

PARTIES

11. **Humana.** Plaintiff Humana is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky. Humana and its subsidiaries are providers of healthcare related services, including insuring risk for prescription drug costs for more than eight million members in all 50 states, the District of Columbia, and Puerto Rico. More than 75% of Humana's total premium revenues in the year 2012 were derived from contracts with the federal government, including Medicare Part D prescription drug coverage and Medicare Advantage plans. Humana operates its insurance businesses through a variety of wholly owned subsidiaries, all of which have assigned their relevant claims in this action to Humana.[7]

[7] Some of the subsidiaries through which Humana conducts insurance business include: Arcadian Health Plan, Inc., CarePlus Health Plans, Inc., Cariten Health Plan, Inc., Cariten Insurance Company, CHA HMO, Inc., CompBenefits Insurance Company, Emphesys Insurance Company, Health Value Management, Inc. d/b/a ChoiceCare Network, Humana Behavioral Health, Inc., HumanaDental, Inc., Humana Benefit Plan of Illinois, Inc., Humana Employers Health Plan of Georgia, Inc., Humana Health Benefit Plan of Louisiana, Inc., Humana Health Company of New York, Inc., Humana Health Insurance Company of Florida, Inc., Humana Health Plan of California, Inc., Humana Health Plan of Ohio, Inc., Humana Health Plan of Texas, Inc., Humana Health Plan, Inc., Humana Health Plans of Puerto Rico, Inc., Humana Health Plan of Ohio, Inc., Humana Insurance Company, Humana Insurance Company of Kentucky, Humana Insurance Company of New York, Humana Medical Plan of Michigan, Inc., Humana Insurance of Puerto

12. **Indivior Defendants.** Defendant Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals Inc. is a Delaware corporation with its principal place of business at 10710 Midlothian Turnpike, Suite 430, North Chesterfield, Virginia 23235. Indivior Inc. is a wholly-owned subsidiary of Indivior plc. Indivior Inc. is engaged in the development, manufacture, and sale of Suboxone throughout the United States and was responsible for the conduct alleged herein. Until on or about December 22, 2014, Indivior Inc. was a wholly-owned subsidiary of Reckitt Benckiser Group plc and was known as Reckitt Benckiser Pharmaceuticals Inc. But on or about December 23, 2014, Indivior plc acquired Indivior Inc., when Indivior plc was demerged from Reckitt Benckiser Group plc.

13. Defendant Indivior Solutions Inc. employed the marketing and sales personnel for the Indivior group of companies. Indivior Solutions Inc. is a separate and distinct Delaware corporation with its principal place of business at 10710 Midlothian Turnpike Suite 430, North Chesterfield, Virginia 23235. It was previously known as Reckitt Benckiser Pharmaceuticals Solutions Inc. On July 24, 2020, Indivior Solutions Inc. pleaded guilty to a one-count felony information, and, together with Indivior Inc. and Indivior plc, agreed to pay a total of $600 million to resolve criminal and civil liability associated with the marketing of Suboxone. The plea and settlement agreement with the government requires Indivior Inc. to disband its Suboxone sales force and never reinstate it.

14. Defendant Indivior plc is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom. Indivior plc's registered agent for service of process is Indivior

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Rico, Inc., Humana Medical Plan of Michigan, Inc., Humana Medical Plan of Pennsylvania, Inc., Humana Medical Plan of Utah, Inc., Humana Medical Plan, Inc., Humana Pharmacy Solutions, Inc., Humana Regional Health Plan, Inc., and Humana Wisconsin Health Organization Insurance Corporation.

Inc., 10701 Midlothian Turnpike, North Chesterfield, Virginia 23235. In the United States, Indivior plc securities trade as American Depositary Receipts on the Over-The-Counter (pink sheet) market (trading symbol INVVY). On or about December 23, 2014, Indivior plc owned, controlled, managed, and operated Indivior Inc.

15. Defendant Reckitt Benckiser Group plc is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103-105 Bath Road, Slough, Berkshire, SLI 3UH, United Kingdom. Reckitt Benckiser Group plc manufactures and markets numerous consumer products, including pharmaceutical drugs subject to FDA approval, and was responsible for the conduct alleged herein. This conduct includes, but is not limited to, the execution of the initial contract with MonoSol in December 2006 that initiated the joint venture to create and manufacture Suboxone film.

16. Defendant Reckitt Benckiser Healthcare (UK) Ltd. is a British company incorporated under the laws of England and Wales. Reckitt Benckiser Healthcare (UK) Ltd. is a subsidiary of Reckitt Benckiser Group plc. Reckitt Benckiser Healthcare (UK) Ltd. established the parameters for the timing of the launch and the formulation of Suboxone film, gathered and investigated all consumer complaints as to Suboxone products, trademarked the names for the financial programs to encourage the switch from Suboxone tablets to film, and, together with MonoSol, obtained patents related to Suboxone film development. Reckitt Benckiser Healthcare (UK) Ltd. approved and paid for each stage of MonoSol's development of the Suboxone film product in the United States, evaluated film samples for MonoSol, monitored the taste and quality of Suboxone film, and manufactured and provided MonoSol with the active ingredients for Suboxone film, along with data, and information. Reckitt Benckiser Healthcare (UK) Ltd. worked on responses to the FDA's concerns about buprenorphine's environmental impact; it

prosecuted patents on Suboxone in the United States Patent Office; it secured at least four United States trademarks on the name Suboxone and the patient assistance program designed to coerce the switch from tablets to film; it scheduled meetings with the FDA and prepared filings to secure United States regulatory approval of Suboxone film; it had numerous interactions with MonoSol in the United States via email and telephone, including weekly teleconferences concerning the strength of MonoSol's patents, and the timing, quality, and United States approval of Suboxone film. Reckitt Benckiser Healthcare (UK) Ltd. also provided grants for the study of Suboxone.

17. On December 23, 2014, Reckitt Benckiser Group plc spun off its pharmaceuticals business, through a demerger transaction, forming Indivior plc. In all relevant respects, Indivior plc is the successor to Defendant Reckitt Benckiser Group plc and has continued, and is continuing, the course of conduct that the other Indivior Defendants began, as alleged herein. In a press release dated February 11, 2015, Indivior plc announced its financial results for the period ending on December 31, 2014, identified the United States market for Suboxone as a key factor in Indivior plc's revenues, and stated that Indivior plc's "priority in 2015 is to continue to build the Company's future prospects by: preserving our Suboxone Film leadership position in the United States . . ."

18. All of Indivior's actions described in this Complaint are part of, and in furtherance of, the illegal fraud, racketeering, monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by Indivior's various officers, agents, employees, or other representatives while actively engaged in the management of Indivior's affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Indivior.

19. **MonoSol.** Defendant Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC is a corporation with its principal place of business located at 30 Technology Drive, Warren, New Jersey 07059. MonoSol changed its name to Aquestive Therapeutics on November 30, 2017. MonoSol is engaged in the development, manufacture, and sale of pharmaceuticals, including Suboxone, throughout the United States.

20. All of MonoSol's actions described in this Complaint are part of, and in furtherance of, the racketeering activity, illegal monopolization and restraint of trade alleged herein, and were knowingly authorized, ordered, and/or undertaken by MonoSol's various officers, agents, employees, or other representatives while actively engaged in the management of MonoSol's affairs (or that of its predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of MonoSol.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States, specifically, the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 28 U.S.C. § 1964(c).

22. This Court has supplemental jurisdiction over Humana's pendent state law claims pursuant to 28 U.S.C. § 1367. The exercise of supplemental jurisdiction avoids unnecessary duplication and multiplicity of actions and is in the interests of judicial economy, convenience, and fairness.

23. This Court has personal jurisdiction over Defendants pursuant to 18 U.S.C. § 1965 because Defendants are present in the United States, do business in the United States, have registered agents in the United States, may be found in the United States, and are otherwise subject to the service of process provisions of 18 U.S.C. § 1965(d). This Court also has personal

jurisdiction over Defendants because Defendants sold Suboxone to Humana in Pennsylvania and directed and made fraudulent statements in Pennsylvania.

24. Venue is proper and appropriate in this district under 28 U.S.C. §§ 1391(b) and (c), and 18 U.S.C. § 1965. Each Defendant resides, transacts business and/or committed an illegal or tortious act in this district, and/or has an agent and/or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out in substantial part in this district.

FACTUAL BACKGROUND

A. The Regulatory Structure for Approval and Substitution of Generic Drugs.

25. The "Hatch-Waxman Act" provides regulatory exclusivity for new pharmaceuticals while providing a pathway for entry of low-priced generic drugs. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the FDA demonstrating the safety and efficacy of the new product. These NDA-based products generally are referred to as "brand-name drugs" or "branded drugs." A drug that receives NDA approval is entitled to regulatory exclusivity for a limited period of time—in other words, the FDA cannot approve any generic drug applications during this period. When the regulatory exclusivity is about to expire, a generic drug company may submit an Abbreviated New Drug Application ("ANDA") that demonstrates that the generic version is essentially the same as the branded version, i.e., it has the same active ingredient, dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

26. A 7-year regulatory exclusivity period for an NDA approved drug can also be obtained by applying for orphan drug exclusivity with the FDA under 21 C.F.R. § 316. Orphan drug exclusivity may be granted: (a) on the basis that a product is intended to treat a disease or

condition that has a United States prevalence of less than 200,000 persons; or (b) where the sponsor can show that there is no reasonable expectation that the costs of developing and making the drug available will be recovered from United States sales, despite the fact that the product treats a disease or condition that has a United States prevalence of 200,000 or more individuals.

27. Generic drugs can be substituted at the pharmacy to fill a prescription for a branded drug. All fifty states and the District of Columbia have drug substitution laws that encourage and facilitate this type of substitution. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense a generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise.

28. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating lower-cost generic competition: generic drugs typically capture over 80% of a branded drug's sales within six months. Generic drugs are usually far cheaper than the branded version—with discounts often reaching 85% or more off the brand price. Thus, generic competition has generated large savings for patients, health plans, and federal and state governments. The Generic Pharmaceutical Association has reported that use of generic versions of brand-name drugs saved the United States healthcare system $265 billion in 2017 alone.

29. Competition from low cost generic drugs saves consumers billions of dollars a year. When a generic drug enters the market, the branded drug often suffers a rapid, steep decline in sales. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics accelerates.

B. Characteristics of the Pharmaceutical Marketplace.

30. State substitution laws were enacted in part because the pharmaceutical market does not function well. In a well-functioning market, a consumer selects and pays for a product after evaluating the product's price and quality. In the prescription drug market, however, a patient can obtain a prescription drug only if a doctor writes a prescription for that particular drug. Because the doctor who selects the drug does not pay for it, he or she generally has little incentive to consider price. Thus, the pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. This "disconnect" arises because the patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

31. State substitution laws are designed to correct this disconnect by shifting the drug selection choice from physicians to pharmacists and patients who have greater financial incentives to make price comparisons.

32. Many branded pharmaceutical manufacturers, including Indivior, exploit this disconnect by targeting marketing efforts at doctors who prescribe medication, rather than at the patients who use the medication. Branded manufacturers employ large forces of sales representatives, who visit physicians' offices in an effort to persuade physicians to prescribe the manufacturers' products. Importantly, these sales representatives do not advise the physicians of the cost of the branded products. Studies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences because they do not pay for the products themselves. The result is a marketplace in which price often plays a comparatively unimportant role in product selection.

C. Suboxone.

33. Indivior obtained FDA approval for Suboxone tablets in 2002. Subsequently, Indivior applied for and received orphan drug exclusivity under 21 C.F.R. § 316 because Suboxone was the first buprenorphine drug approved for the treatment of opioid addiction and Indivior claimed that it would not recover the costs of developing the tablets.

34. Despite telling the FDA that it would never recoup these costs, during its 7-year period of exclusivity, Indivior garnered over one billion dollars from marketing and selling Suboxone tablets in the United States. This is far above the commercial potential that typically entitles a drug company to orphan drug exclusivity.

35. But seven years of huge profits was not enough for Indivior.

36. As Indivior's seven-year orphan drug exclusivity for Suboxone tablets was set to expire on October 8, 2009, Indivior knew that less-expensive generic competition would likely arrive given the lucrative Suboxone market. In fact, multiple generic manufacturers sought FDA approval to market generic versions of Suboxone tablets.

37. The prospect of generic competition was alarming to Indivior because Suboxone was extremely profitable and formed a substantial portion of Indivior's revenue and profits. Indivior knew that generic competition posed a substantial threat to those profits. Indivior projected that it would lose 80% of its Suboxone tablet sales to generic Suboxone in the first-year generic tablets were on the market, with further revenue and profit erosion thereafter.

38. Indivior devised a strategy to develop a new dosage form of Suboxone and submit another NDA on this new form, thereby allowing Indivior to enjoy patent and regulatory exclusivity on this new product. While legitimate follow-on formulations may occur in the pharmaceutical industry—e.g., to introduce a better or safer form of a drug—Indivior instead used fraud, coercion, and racketeering in its Suboxone Scheme to convince patients, their doctors

and health plans to switch to a new formulation that was less effective than existing tablets, but more dangerous, particularly with regard to accidental ingestion by children. The objective of Indivior's product-hopping scheme was to frustrate automatic substitution and maintain its monopoly.

D. The Suboxone Scheme.

39. In its search for ways to extend its monopoly power for Suboxone, Indivior found a partner: MonoSol. MonoSol's sole offering as a business is its drug delivery formulation—a sublingual film. Using this technology, MonoSol's business model is to encourage companies, like Indivior, to use its dosage form to extend exclusivity:

a. "Patient-friendly delivery with no generic substitution"

b. "Partnering with MonoSol Rx offers pharmaceutical companies the ability to introduce products that are highly differentiated from other dosage forms, both in performance and marketability, creating fresh, dynamic revenue-generating opportunities."

c. Mock quote used in advertisement: "We launched this brand 5 years ago. We're not just letting it go over the cliff. It's time for the new strategy."

d. "PharmFilm formulations represent revenue-life cycle extensions for products with patent lives that have expired or are approaching expiration."

e. "If patient-friendly delivery, patent expiry, or launching the next blockbuster is on your agenda, the time is right to consider the advantages of PharmFilm."

f. "Because PharmFilm is a unique, patent-protected delivery technology, it can be an ideal strategy for extending the life of a brand as generic incursion approaches."

g. "PharmFilm drug technology allows: no generic substitution."

40. In December 2006, Indivior and MonoSol executed an initial contract that initiated a joint venture to create and manufacture Suboxone film, using MonoSol's proprietary PharmFilm technology. MonoSol negotiated with Indivior to receive royalty payments on the sales of Suboxone film.

41. Indivior and MonoSol's development of the new sublingual film was intended to thwart generic entry and to maintain Suboxone's monopolistic market share by extending Indivior's exclusivity on a Suboxone product. But, then, Indivior and MonoSol's dealings took a darker turn.

42. Between December 2006 and March 2007, Indivior and others discussed ways to delay FDA approval of generic versions of Suboxone tablets by raising false safety concerns about Indivior's ***own*** Suboxone tablets, and then discontinuing tablets under the pretext of those safety concerns. This would have the effect of triggering the FDA safety-related processes that could take as long as a year to resolve. They wrote, "We could tie up generic for 1 year. . . . When we file for film and withdraw tablet [the FDA] is precluded from approving another tablet until they have made a determination in response to a petition from generic company to determine that product was not withdrawn for safety or efficacy." A "negative safety issue" could "prevent approval of generic[.]" "We need to think creatively about a safety story;" "we probably also need to think very negatively about [tablets] and identify aspects that could be unsafe[.]" "We cannot prevent generics . . . We can delay[.]" They also provided a timeline for how long generics could be delayed.

43. And delay generics they did. In July of 2007—more than two years before its orphan drug exclusivity expired—Indivior announced to the FDA that it planned to apply to market a sublingual film version of Suboxone.

44. On October 20, 2008, Indivior submitted a new NDA to the FDA to market the sublingual film version of Suboxone.

45. While awaiting FDA approval of Suboxone film, Indivior's managers drafted marketing plans for the drug. Between May 2009 and August 2010, the draft plans listed "Key

Success Drivers" for Suboxone film such as "Driving physician prescriptions for Suboxone film," "Driving formulary support for Suboxone film through payors," and "Driving patient Suboxone film trial."

46. Driving formulary support for Suboxone film through payors—like Humana—was a key goal of the Suboxone Scheme because third-party payors like Humana were the ultimate source of Indivior's profits.

47. On or about June 9, 2009, Indivior's Medical Director told fellow Indivior medical personnel, "We need to develop a *story* about childhood exposures to set the stage for switching patients to" Suboxone film, once again confirming that safety concerns relating to the tablet was only a ploy force the market to switch from Suboxone tablets to Suboxone film. The fabricated "safety story" became central to the Suboxone Scheme.

48. On or about October 5, 2009, Indivior sent a letter to the FDA asking whether the FDA agreed that Suboxone film's packaging would protect against diversion (e.g., illegal selling, sharing, and smuggling of Suboxone) and accidental child exposure (i.e., children taking Suboxone by accident). The FDA did not immediately respond. Indivior executives and others internally discussed that the FDA could disagree, for reasons including "there is an incremental risk of the film since once a child ingests the film it will be nearly impossible to remove vs. tablets," and it was not clear how physicians would use the serial numbers on Suboxone film packages to deter diversion.

49. On or about November 24, 2009, Indivior resubmitted its NDA for Suboxone film to the FDA, including a revised Risk Evaluation Management Strategy ("REMS") to address safety concerns related to the film product. MonoSol remained active in the NDA-approval

process and committed to doing everything it could to enable FDA approval as quickly as possible.

50. On or about January 22, 2010, Indivior's Chief Executive Officer told company executives, "Our immediate focus is to get the FDA approval for [Suboxone film] asap to switch the business ahead of the generic."

51. On or about March 29, 2010, the FDA responded to Indivior's October 5, 2009 letter, rejecting Indivior's claim that Suboxone film's packaging would protect against diversion and accidental child exposure:

> The Agency will not comment on whether the serial numbers [on Suboxone film's packaging] would lead to a decrease in diversion of a drug product, because drug diversion issues are regulated by DEA.
>
> ***
>
> No, we do not agree that the packaging for [Suboxone film] provides meaningful incremental protection against pediatric exposure. Although the foil pouches fulfill the child resistant effectiveness standards and the foil pouch bears warning statements alerting patients to keep out of reach of children, no data were provided to support that these measures will encourage patients to store [Suboxone film] in a manner which prevents accidental pediatric ingestion. Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial dose[s] that are neither in the child-resistant pouch nor in a child-resistant medical bottle. Furthermore, because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.

52. Indivior's executives, managers, and personnel understood from the FDA's response that they lacked substantiation to inform health care providers that Suboxone film was safer than alternative drugs such as tablets. Indivior executives and managers wrote to each other, "The FDA has stated that we have no proof that patients will not take the film out of the [pouch] and cut it into multiple doses. Thus not reducing potential exposure . . . . Even then the FDA points out that the film may not be swallowed thus making more buprenorphine

available[.]" Indivior's executives and managers recognized that the FDA's response could "be a bigger issue as it may imply the overall risk/benefit is not favorable for our film (vs tablet);" and noted "[i]t looks like they [the FDA] are trying to deny us the ability to make a claim on additional pediatric safety of the film."

53. With regard to misuse, abuse, and diversion, Indivior executives, managers, and personnel knew that Suboxone film's thin form potentially could make it easier to conceal, and thus more susceptible to smuggling than tablets. They also knew that the film's individual packaging could make it more portable, including for reselling and sharing, and that the serial numbers on the pouches were not electronically tracked or shown to deter diversion.

54. With regard to accidental child exposure, Indivior knew that Suboxone film had attributes that potentially could make it more dangerous to children, including that it stuck and could not easily be spit out if accidentally taken by a child; dissolved more rapidly, leaving less time to remove it from a child's mouth before absorption; had higher bioavailability at certain doses, potentially increasing the severity of an incident; was formulated to taste better, reducing the likelihood that a child would seek to remove it; and could not easily be re-secured in its original packaging, which, unlike a bottle with a child-resistant cap, was not designed to be re-closed.

55. Indivior submitted its REMS to address the FDA's safety concerns, and the FDA approved Indivior's application to market the film formulation on August 30, 2010. This included approval of the REMS and prescribing information for the drug. None of these materials, however, stated that Suboxone film was safer than alternative drugs such as tablets, or reduced the risk of misuse, abuse, diversion, or accidental child exposure. Nevertheless, Reckitt Benckiser Pharmaceuticals Inc.'s Chief Executive Officer told its parent company Reckitt

Benckiser Group plc's executives, including its Chief Executive Officer and Chief Financial Officer, "We will be making the most of every minute between now and generic approval to convert our tablet business to film," including a "Full Blitz campaign for salesforce through Thanksgiving." For the "Full Blitz" campaign, Indivior's salespeople planned to raise "diversion and misuse and pediatric safety" in sales presentations to physicians, even though there were no scientific studies to establish that Suboxone film was safer with regard to diversion, misuse, or pediatric safety.

56. Indivior initiated this "Full Blitz" campaign, including the false pediatric safety story, despite the fact that it knew the risks Suboxone film posed to safety and that the film formulation offered no medical or clinical benefits over the existing tablets.

57. From a treatment perspective, the film was, at best, equivalent to the tablets. Until August 2012, its dosage strengths were the same as the tablets. In fact, Indivior obtained FDA approval of the film version of Suboxone based almost entirely on previous studies that it used to establish the safety and efficacy of the tablets. Indivior performed no efficacy studies on Suboxone film itself. Indivior simply showed that the film version had sufficiently equivalent bioavailability compared with the tablet version. The FDA confirmed that Indivior's NDA contained no new efficacy studies. And Indivior itself told the FDA that any differences between the film and the tablet were "clinically insignificant."

58. In fact, in many respects the film formulation had numerous *drawbacks* compared to the tablets. Naloxone bioavailability with the film version was increased relative to the tablet version. This increased the risk of unwanted opioid withdrawal symptoms—the very condition Suboxone is designed to treat—and decreased the likelihood of successful induction and stabilization of patients taking the film. The film formulation was also easier to dissolve and

inject than the tablet formulation, defeating one of Suboxone's major "virtues"—low abuse potential.

59. The new film formulation was also easier to conceal than the tablet, and thus more susceptible to diversion. For example, because Suboxone film strips are flat, they can easily be placed under stamps, in bindings of books, and in hems of clothing and smuggled into jails and prisons. In fact, Indivior learned before the FDA approved Suboxone film that almost 6,000 strips (46% of those dispensed to study patients) were "missing" after the limited clinical studies Indivior performed to support FDA approval.

60. Nor did patients prefer Suboxone film to Suboxone tablets; they preferred the tablets by a wide margin. The film formulation was more irritating than the tablet to a patient's oral mucosa, and the taste of the film was described by some patients as too strong. The film also gummed up on patients' fingers when handled, was prone to blowing away in the wind when opened outdoors, and was harder to divide into partial doses. The wrappers were also hard to dispose of at work without co-workers finding out that patients were taking Suboxone.

61. None of that mattered to Indivior. It began aggressively marketing Suboxone film shortly after obtaining the FDA's approval, using a host of fraudulent and anticompetitive tactics to cause doctors to switch prescriptions from Suboxone tablets to the non-substitutable Suboxone film, in order to force the market to stop purchasing Suboxone tablets and begin purchasing Suboxone film.

62. The fact that Suboxone film was inferior to Suboxone tablets caused Indivior very substantial public relations and commercial problems. Indivior needed to somehow justify the hard product switch to the public, to doctors, and payors during its initial marketing blitz.

E. Indivior's Fraudulent "Safety Story" Marketing Blitz Conducted Through the Activities of Indivior Solutions Inc.'s Sales Force.

63. Indivior and MonoSol concocted the idea that Suboxone film was safer than Suboxone tablets for children who are accidentally exposed to the product. But, Suboxone film itself is far less safe for children than Suboxone tablets—as the FDA concluded when this issue was brought to them. So Indivior focused on the idea of selling Suboxone film in single-serving packets (so-called "unit-dose" packaging) and asserting that this packaging made the product safer than the tablets, which Indivior sold in the United States in child-resistant bottles that hold multiple tablets. There are many more examples of materially false and misleading statements that Indivior made, which have been included in the criminal information of Reckitt Benckiser Pharmaceuticals Inc.'s (later Indivior plc's) Chief Executive Officer[8] and the criminal indictments of the company, incorporated by reference, including those below.

64. On or about September 2, 2010 (about three days after Suboxone film received FDA approval), Reckitt Benckiser Group plc's Chief Executive Officer emailed approximately twenty Indivior executives and managers, including Reckitt Benckiser Pharmaceuticals Inc.'s Chief Executive Officer and marketing personnel, stating that Suboxone film was "safer," and encouraging them to "convert [patients] from tablets to films, thereby protecting [Indivior's] Net Revenues in the USA."

65. This was the beginning of Indivior's massive nationwide mail and wire fraud racketeering effort to use Indivior Solutions Inc.'s United States sales force to coerce physicians, patients, and health plans to switch from Suboxone tablets to Suboxone film.

[8] On June 30, 2020, Indivior plc's Chief Executive Officer pleaded guilty in Virginia federal court to a misdemeanor for failing to prevent the company from giving misleading safety statistics about how often children were accidentally poisoned by the drug to Massachusetts officials as part of a marketing campaign for Suboxone film. The misleading statistics made it seem safer than comparable treatments in pill form, and the Chief Executive Officer failed to correct the record at the time.

66. Indivior Solutions Inc. employed the marketing and sales personnel for the Indivior group of companies. On or about September 6, 2010 (about a week after Suboxone film received FDA approval), an Indivior Solutions Inc. national sales supervisor emailed approximately fifty Indivior salespeople, encouraging them to tell physicians that Suboxone film was "safer because of the packaging."

67. On or about October 17, 2010, Indivior's Chief Executive Officer told Indivior personnel to revise the performance appraisals and incentive programs for salespeople to reward "film sales only." He stated that Indivior's salespeople had "every possible resource to enable them to generate demand for a scheduled narcotic that is being given away for free to an addicted population," and those without "adequate film sales" may be fired. Thereafter, Indivior Solutions Inc. revised the performance appraisals and incentive programs to be based primarily on the percentage of Suboxone film compared to tablet sales in the salesperson's territory (sometimes called the "film market share" or "film share").

68. On or about October 25, 2010, Indivior Solutions Inc.'s sales supervisors discussed baseless "dialogue points" that Indivior salespeople were using to highlight Suboxone film's "advantages" to physicians and pharmacists, which included "Reduced misuse/diversion" and "Public safety-reduced pediatric exposure." On or about November 3, 2010, an Indivior Solutions Inc. sales supervisor emailed the dialogue points to Reckitt Benckiser Pharmaceuticals Inc.'s Chief Executive Officer.

69. In or about December 2010, Indivior's Vice President for Clinical Affairs met with physicians in California and elsewhere, and, in the presence of Indivior salespeople, materially falsely and fraudulently stated to the physicians that Suboxone "Film addresses child safety and abuse and diversion" and was a "safer product."

70. On or about March 11, 2011, Indivior's Chief Executive Officer materially falsely and fraudulently stated in Indivior's 2010 Annual Report that Suboxone film was "better from a child safety point of view, mak[ing] it more attractive for doctors to prescribe."

71. Throughout the relevant time period, Indivior Solutions Inc.'s sales representatives continued to make false and fraudulent statements in order to induce and, in some cases, coerce, physicians, pharmacists, and other health care providers to prescribe and dispense Suboxone film and recommend the prescribing and dispensing of Suboxone film. The following non-exhaustive list are statements and representations sales representatives made to health care providers and used as models for other Indivior sales representatives to promote Suboxone film:

a. On or about September 1, 2010, an Indivior sales representative in New York told physicians that Suboxone film "offers increased protection against misuse/abuse/diversion and pediatric exposure. Due to this, and the fact that patients will be able to get the film at no cost, they have all stated that they will prescribe the Film when it is available. . . . Most pharmacists have also been impressed with the new formulation and the steps the company has taken to decrease diversion and pediatric exposure."

b. On or about September 10, 2010, an Indivior sales representative in North Carolina told a physician that Suboxone film "offers greater protection against pediatric exposure & misuse/diversion."

c. On or about September 30, 2010, an Indivior sales representative in South Carolina met with a physician and "[d]iscussed pediatric exposure & tablet diversion as reasons for MD to insist that pts switch from tablet to film."

d. On or about December 16, 2010, an Indivior sales representative in Michigan told physicians that Suboxone film is the "safest choice," has "less chance of inadvertent use by kids," can "protect the community;" and can "protect office-based treatment" from being banned.

e. On or about December 21, 2010, an Indivior sales representative in California told physicians that Suboxone film "is a better safer medication" and "it would be unethical or inappropriate for us to promote the tablet now that we have a better, safer product."

f. On or about December 22, 2010, an Indivior-paid speaker told physicians in Michigan that her "big plus for the Film was the packaging and therefore making it a safer product for the community."

g. On or about December 22, 2010, an Indivior sales representative in Tennessee told physicians that during the holiday season, Suboxone film gives patients "added comfort in knowing their medication is safer to have in the home as family and friends with small children will be visiting more."

h. On or about January 6, 2011, an Indivior sales representative in Michigan met with a physician who was "in the category of trying out the film but not yet sold on it," and stated that "it's important [for the physician] as a physician and mom to convert patients to the Film. The fact that film helps to protect [office-based opioid treatment] and reduces pediatric exposure appeared hard to ignore for the doctor. Hopefully that message will have a louder voice in her head than the patients telling her they are 'happy' with the Tablet."

i. On or about January 11, 2011, an Indivior sales representative in California told physicians and pharmacists that Suboxone film is a "safer product vs tablet."

j. On or about February 3, 2011, an Indivior sales representative in Indiana told a physician that patients who request tablets do so "in order to divert them. [The physician] said that he may have become a bit too trusting in his several years of treat[ing] patients. We spoke about how the Film can 'weed out' those patients truly not committed to recovery. He promised to convert ALL patients to Film."

k. On or about February 3, 2011, physicians told an Indivior sales representative in Utah that patients were "complaining about the Film and asking to be put back on the tablet." Indivior's sales representative responded by discussing "misuse and abuse of Suboxone tablets and how the Film is the better, safer choice. I know that we will have more followup [sic] in this office, due to these doctors' new awareness of what is really happening when some ask to be switched back to the tablet."

l. On or about February 9, 2011, an Indivior sales representative in Texas told physicians "that many other doctors are going 'film only' because they want to provide the best quality care to their patients with the most efficacious, safest, and cost saving treatment and it has influenced several of them and they then have been interested in how others are doing this, how patients are responding, etc. I believe it makes them feel more confident to know that others are doing this and it also makes them want to do the same to keep up with 'quality care' physicians."

m. On or about March 2, 2011, an Indivior sales representative in Texas told physicians that Suboxone film is "newer, easier, quicker and most importantly safer for the patients and their families, the physicians and community."

n. On or about March 2, 2011, an Indivior sales representative in Indiana met with a pharmacist and "had a candid discussion as to why some patients want so badly to stay on the tablet even at a higher price to them (diversion). [The pharmacist] is going to 'hammer away' at [doctors who prescribed tablets] to get these patients on Film."

o. On or about April 13, 2011, an Indivior sales representative in Illinois told a physician and a pharmacist about "some of the blogs [he has] read and about the reported child death. This seemed to really impact them, and [the physician] said he has had some concern about a few patients in the past. We discussed that while the film cannot stop misuse and diversion, it can help prevent it, and our hope is to decrease the misuse and diversion, as well as the number of pediatric exposures. The pharmacist in the building also attended the [presentation] and everyone agreed that if a patient came to the pharmacy with a prescription for the tablet, the pharmacist would call back the office to see if it could be switched to film."

p. On or about April 14, 2011, an Indivior sales representative in California told a physician that Suboxone film is "safer, better, and cheaper than the pills. What reason do you have not to convert all of your patients to the film? She could not give a reason. She said she will switch her patients."

q. On or about May 10, 2011, an Indivior sales representative in California told a physician that she would not help the physician enroll in a patient-referral program "unless I knew those patients seeking treatment would get a Comprehensive approach that includes the Safest Medication on the Market for Opioid Dependency which is the Film."

r. On or about May 26, 2011, an Indivior sales representative in Utah told physicians that Suboxone film is "safer to have around their family members."

s. On or about June 8, 2011, an Indivior sales representative told physicians in Virginia that one doctor in the area "converted all patients to Film and no longer give[s] a choice [between tablets and film] due to rampant diversion of the tablet in the area, which borders Virginia, Kentucky and Tennessee. This has been a great win and is something that I've been able to tell all my other docs who have converted most of their patients but not all."

t. On or about July 7, 2011, an Indivior sales representative in North Carolina met with a physician who was "still giving [some] patients the choice between the Suboxone Film and tablet . . . . I strongly encouraged [the physician] to protect herself, her practice and her medical license by prescribing Suboxone film to ALL of her patients. I said, 'I don't want any of my physicians to find themselves on a witness stand defending their decision for prescribing Suboxone tablets which caused the death of a child.' Hopefully that statement convinced [the physician] to adopt a fail first policy on the Suboxone film."

u. On or about July 7, 2011, an Indivior sales representative in Oregon asked a physician what was "holding [him] back from the patient-preferred Film?" The physician stated that his "tablet patients are doing well and are afraid of changing when they are doing well." The sales representative then "talked about Tablet exposures to children and how [the physician] can be their safety net by prescribing the Film rather than the Tablets which he agreed with."

v. On or about July 7, 2011, an Indivior sales representative in California was "working diligently with [a physician] in order to get him to transition his considerable amount of tablet patients to the Film. I am making progress with him. He's been reluctant and has allowed his patients the choice [between tablets and film]. I believe I've instilled in him the importance of protecting public safety and [office-based opioid treatment], and how, by prescribing the Film, he will help to make that happen."

w. On or about July 18, 2011, an Indivior sales representative in Pennsylvania "had an excellent conversation with [physicians] around more of the reasons why [they] might want to move more of their patients off of tablets and onto the Film. The agreed it was a safer option and are proud they are doing their part to protect our community."

x. On or about July 21, 2011, an Indivior sales representative in Delaware met with physicians and pharmacists, "capitalizing on the Public Health Message and the importance of providing patients with a safer option in the film."

y. On or about July 21, 2011, an Indivior sales representative in Pennsylvania told physicians, "You get the same clinical efficacy [with Suboxone film] as you get with tablets, possibly greater compliance with improved taste and dissolve time, safety is improved within the public and the home, and most patients get the Film for virtually free with the Savings program. Why take the chance?"

z. On or about September 2, 2011, an Indivior-paid speaker in Maryland told physicians that Suboxone film was "preventing pediatric death in graphic terms."

aa. On or about October 26, 2011, an Indivior sales representative in Tennessee "led physicians to the internet so that they may see how their decisions to prescribe any tablet over [Suboxone film] may have a negative impact on the community. There are current articles that [the tablet] kills children all over the internet and this helps them to see the reasons to prescribe [Suboxone film] over the tablets. . . . One of my doctors . . . still has not converted all of his patients to [Suboxone film]. He was able to visit the internet article to see how [Suboxone film] could put safe guards in the community as well as in his practice. Once he saw this information he committed to write all of the [tablet] patients [Suboxone film]. From the look on his face [he] was really concerned about the safety of his patients."

bb. On or about November 11, 2011, an Indivior sales representative in Virginia made the following presentations to physicians: "The physicians agree that we all have an obligation to protect the public health. I have each physician [say] if they agree that it starts with THEM, the prescriber? They do agree. Then WHY would you not prescribe the SAFEST medication available? Is it worth the risk of pediatric exposure? Is it worth the risk of abuse and diversion? Is it worth the risk of ending office based treatment? It starts with YOU, DOCTOR! Unfortunately, it does NOT end with you! It can end with unintended consequences in the hands of people suffering from a terrible disease, who are not known for making the best decisions! These discussions have really opened the eyes of quite a few physicians who now

realize their obligation." An Indivior sales supervisor singled out this presentation as a model presentation, forwarding it to other Indivior salespeople.

cc. On or about December 5, 2011, an Indivior sales representative collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone film from others across the region (in Illinois, Indiana, Kentucky, Michigan, Ohio, Tennessee, and West Virginia), including "Baby Death articles;" "Diversion with Tablets and high street value of $25.00 per pill;" "Film harder to sell on streets;" "if patients call office and ask if doctor writes the tablets (or pills) that is a patient you do not want—they will be diverting and your office can or will be tied to that illicit drug;" "I inform my doctors (and pharmacists) that insurance companies are beginning to view the film the same way we do . . . as the superior (safer) product;" "I focus on the safety for their office as well as the general public, the fact [Suboxone film] will weed out the drug seekers and it will make their offices respectable and full of patients who are serious about their recovery;" and "Patients are tempted to share especially when they are doing well and want to help people that they care about . . . [Suboxone film] will reduce this possibility."

dd. Throughout 2011, Indivior sales representatives collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone film from others across the region, including "Once the dialogue opens up about community, safety etc, I explain that we believe [Suboxone film] is the safest medication available;" "[by] providing the safest medication (FILM) you (physician, pharmacist, counselor, office staff) are helping the patient 'close the gaps' in their treatment as well as reducing the chance of misuse, abuse and diversion, which increases public safety;" "Do you agree the Film is safer and less abusable than the tablet?;" "[Suboxone film is] a safer alternative to the tablet — safer for the patients, safer for their families and more aligned with [Indivior's] goal to protect office-based treatment;" and asking physicians "to imagine how devastated [their] patients would be if one of those children were to get into a bottle full of Suboxone tablets."

72. Indivior's written marketing materials used to promote Suboxone film also contained materially false and fraudulent statements and representations, including the following:

a. Suboxone film was "Helping Address Public Health Needs;"

b. Suboxone film could "Help Address Misuse and Abuse;"

c. Suboxone film "Can Be Part of the Solution" to "misuse," "diversion and abuse," and "unintentional pediatric exposure;"

d. "Nearly half of Suboxone Film prescribers surveyed cited 'potential for reduction of abuse and diversion' as a reason to prescribe vs Suboxone Tablet," when in fact,

only 28% of the prescribers had cited that supposed reason (in the study described below), many of them after receiving fraudulent sales presentations from Indivior;

e. A false and fraudulent chart with the heading, "Suboxone Film—Helping to Reduce the Risk of Pediatric Exposure," that purported to depict pediatric exposure data for Suboxone tablet and Suboxone film, but intentionally omitted other data from the same study that showed that buprenorphine-only tablets also had low pediatric exposure, and therefore undermined the claim that Suboxone film reduced pediatric exposure. An Indivior employee asked Indivior's Medical Director, Timothy Baxter, "I couldn't help but notice that the chart did not show the [buprenorphine-only tablets] line. Does that mean we can also show the graph without [that] line? That would make such a huge difference!" Timothy Baxter responded, "That chart is now published so nock [sic] yourself out!"

f. A false and fraudulent pair of charts with the heading, "Suboxone . . . Film—associated with lower rates of diversion and abuse . . ." that purported to depict diversion and abuse data for Suboxone tablet, buprenorphine-only tablets, and Suboxone film, but intentionally omitted two other charts from the same page of the same study that showed that Suboxone tablets and buprenorphine-only tablets had diversion and abuse rates similar to Suboxone film during certain time periods, and therefore called into question Indivior's claim that Suboxone film was associated with lower rates of diversion and abuse.

73. Nor were these misrepresentations limited to marketing personnel. On or about April 13, 2011, Indivior's Chief Executive Officer materially falsely and fraudulently stated in a corporate newsletter that Suboxone film "has the potential for greater child safety."

74. In or about July 2012, at a Reckitt Benckiser Group plc investor presentation, in the presence of Reckitt Benckiser Group plc's Chief Executive Officer, Indivior's Chief Executive Officer materially, falsely and fraudulently stated that Suboxone film was "less divertable [sic] and abusable."

F. Suboxone Film Was Not Safer for Children

75. Indivior's "child safety" rationale was a complete fabrication and pretext. Indivior's sole reason for reformulating the product from tablets to film was to impair generic competition and maintain its monopolistic profits. And the unit-dose packaging brought no added measure of safety.

76. Indivior repeatedly and expressly stated that its true purpose in reformulating Suboxone and its packaging was to protect Indivior's long-term Suboxone profits by delaying and impairing generic competition. Thwarting generics, not protecting children, was Indivior's real goal. For example:

a. Indivior's 2007 Annual Report states that the revenue and income of the Suboxone business "may not be sustained going forward unless replaced with new . . . forms on which [Indivior] is actively working."

b. Indivior's 2008 Annual Report states that it "continues to search for ways to offset the impact of the loss of exclusivity in the USA at the end of September [sic] 2009, up to 80% of the revenues and profits of that business might be lost to generic competition in 2010, with the possibility of further erosion thereafter."

c. Indivior's 2010 Annual Report states: "[I]n the event of generic competition to the Suboxone tablet, the Group expects that the Suboxone sublingual film will help to mitigate the impact thereof."

d. Indivior's 2010 Annual Report also states: "It is well known that by far the largest part of the Pharmaceuticals business, the Suboxone tablets in the USA, can become subject to generic competition at any time. To mitigate the potential impact of this, in August 2010 we launched a patent-protected . . . Suboxone film."

e. Similarly, Indivior's 2011 Annual Report states: Indivior "has developed a new and patented sublingual film delivery method for this product which partially mitigates the risk exposure from the expected generic variant entry against tablets."

77. If Indivior really believed that unit-dose packaging was necessary to protect children from accidental exposure to Suboxone, Indivior would have sold its Suboxone tablets in unit dose packages. Indivior had known since at least 2004 that some children were accidentally exposed to Suboxone tablets in the United States. Yet, Indivior continued to sell Suboxone tablets in multi-unit bottles, rather than unit-dose packages, for almost ten years. Indivior's "epiphany" that unit-dose packages are safer occurred only when it became useful to Indivior in impairing generic competition.

78. Indivior has admitted to the FDA that, during the time that Indivior was busy reformulating the product from tablets to film, Indivior knew that it was feasible for it to market the tablets in unit-dose packages. Again, it did not.

79. Indivior nonetheless sold Suboxone tablets in unit-dose packages throughout much of the rest of the developed world. Indivior gained approval to sell unit-dose-packaged Suboxone tablets in the European Union in 2006 and in Canada in 2007. The tablets that Indivior sells in the European Union and Canada have the same formulation, in all material respects, as the formulation that Indivior sold in the United States. If Indivior genuinely believed that unit-dose packaging was necessary to prevent accidental exposure to children, nothing stopped Indivior from seeking similar approval for that packaging in the United States.

80. Until FDA approval of generic Suboxone tablets was imminent, Indivior never told or suggested to the FDA that tablets in multi-unit bottles presented an undue safety concern for children. Instead, in June 2009, Indivior told the FDA that Indivior had worked with state and federal agencies, and with medical societies, to assure responsible distribution of Suboxone tablets "through a qualified and monitored distribution system designed to assure safe use" of those tablets. In a REMS document that Indivior submitted to the FDA in connection with Suboxone tablets, Indivior asserted that the existing REMS would "assure safe use" of Suboxone tablets.[9] As late as August 2012, Indivior officially reported to the FDA that distribution of its own tablets in bottles, pursuant to the REMS then in effect, was safe and required no changes.

81. In 2012, Indivior commissioned a study to test this theory. It hired contractors to review telephone calls to poison control centers that involved Suboxone. This study was, at best, inconclusive. In fact, it was described by the Indivior manager overseeing the project as a

[9] REMS submission to FDA dated December 22, 2011, at p. 1.

"worthless, empty shell." In instances in which it is possible to tell whether the exposure was to single, partial, or multiple doses of Suboxone, exposures to single or partial doses predominated. The FDA later confirmed this data; the FDA studied 131 instances in which it was possible to tell whether the child had been exposed to single, partial, or multiple doses. Only nineteen of those 131 exposures (14.5%) involved multiple doses.

82. The data showing that most accidental exposures are of single or partial doses further highlight the pretextual nature of Indivior's alleged safety concern. At all relevant times Indivior knew that unit-dose packaging may be substantially less effective than multi-unit bottles in protecting children from the far more predominant exposures to single or partial doses. Unlike a child-resistant bottle, once a unit-dose package is opened, there is no safe place to put the unused single or partial dose. This is particularly a problem with Suboxone because Indivior sold the tablets in only 2mg and 8mg dosages. A typical Suboxone regimen will start the patient on the 8mg dose, then scale the dosage down in 2mg increments every month or so. Thus, patients must break the 8mg tablet or film apart in order to get the 6mg and 4mg dosages. Unit-dose packaging leaves the patient with no secure place to put these unused portions. For these reasons, among others, the FDA specifically concluded that it could "not agree that the packaging for [Suboxone] sublingual film provide[d] meaningful incremental protection against pediatric exposure."[10]

83. Indivior's alleged safety concerns are further shown to be pretextual because Suboxone film itself—regardless of the packaging—is substantially more dangerous to children than tablets. The film turns into a gel within thirty seconds and fully dissolves within three minutes. Thus, children who accidentally place Suboxone film in their mouths tend to absorb it

[10] Suboxone sublingual film, ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS, p. 27, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022410Orig1s000AdminCorres.pdf.

quickly and completely. Moreover, children have a hard time spitting out the film. In contrast, Suboxone tablets may take up to ten minutes to dissolve, and children often spit them out, terminating their exposure.

G. Indivior Tries to Destroy the Suboxone Tablet Market.

84. This fraudulent marketing blitz would not work fast enough for Indivior to convert the patient population before generic drugs came into the market. Indivior needed to switch them faster, so it raised the price of the Suboxone tablet above that of the film.

85. Starting in or about 2010, Indivior significantly raised the price of Suboxone tablets, but it did not increase the price of Suboxone film, thus creating an artificial price difference to push patients to switch from the tablets to the film. For example, in or about October 2011, an Indivior manager told colleagues, "I could not support a tablet [price] increase again before next October. That would be essentially another 37% over 24 months. . . . If we are considering the patient in all of this, then we need to understand that 40% will have to remain on the tablet due to supply constraints . . . . We also need to consider the public health backlash and that of physicians." Yet, in early 2012, Indivior charged an average price of $140.00 for a thirty-count bottle of the 2mg tablets and $252.00 for the 8mg tablets, and in or about July 2012, Indivior implemented a 15% price increase on the tablets to $161.70 for a bottle of the 2mg tablets and $289.80 for the 8mg tablets. But Indivior left the price of Suboxone film steady at $117.85 for a thirty-count carton of the 2mg films and $211.1 for the 8mg films. Including the effects of previous price hikes on the tablets, this created a total 27% difference in prices between the tablets and the film. Of course, the "savings" to consumers (and Humana) from the nominally lower prices on the branded film compared to the tablets was entirely an illusion. Absent Indivior's Suboxone Scheme, consumers (and thus Humana) could have bought generic Suboxone tablets at a 70%–90% discount to the branded tablets.

86. On or about September 14, 2012, Indivior executives perpetrated a public relations strategy to discontinue the Suboxone tablet, indicating that Indivior would use the "[p]erception of discontinuation as a means for blunting generic/competitive entry" and convey a "'[w]e must be responsible' sentiment." On or about the same day, Indivior's contractors provided Indivior with a three-page "executive summary" that failed to include any finding that Suboxone film was safer than tablets with regard to accidental child exposure, or caused any drop in exposures. The summary stated that there were fewer references to Suboxone film than tablets in the telephone call notes, but the reasons for this could not be determined, and "any results related to the original packaging should be interpreted with considerable caution" because many of the notes did not indicate whether the drug had been in the packaging or left outside the packaging by an adult.

87. But the Defendants' plan for the Suboxone Scheme was not complete—Defendants still planned to covert the majority of Indivior's patients to the film.

88. On or about September 18, 2012, Indivior sent a "Notice of Discontinuance" of Suboxone tablet to the FDA, stating the reason for the discontinuance was "increasing concerns regarding pediatric exposure to" Suboxone tablet. Indivior and its respective Chief Executive Officers approved the notice, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

89. On or about September 25, 2012, Indivior issued a press release falsely advising the public and doctors that Indivior intended to withdraw the tablets from the market within the next six months "due to increasing concerns with pediatric exposure." Indivior's executives approved the press release, even though they knew the discontinuance was designed to force the market to switch to Suboxone film and delay FDA approval of generic Suboxone tablets.

Indivior instructed its sales force to deliver the same fraudulent message to doctors and other industry participants, asserting that Indivior would imminently withdraw the tablets from the market due to child-safety concerns. In fact, the FDA determined that there was no evidence that the tablets "were, or should have been, withdrawn from sale for reasons of safety."[11]

90. Indivior's real and sole purpose in announcing the imminent withdrawal of the tablets from the market was to further coerce doctors to switch their prescriptions and prescribing habits from the tablets to the film, and to do its best to effectuate a hard switch in the market from tablets to film.

91. On or about September 18, 2012 through 2019, Indivior prepared letters, signed by Indivior's Medical Director, sent through the United States mail and used to promote Suboxone film, that contained materially false and fraudulent statements and representations, including the following:

a. " Dear Patient . . . The decision to take Suboxone Tablets off the market was a voluntary choice made by [Indivior] as a result of recent information the company received showing higher rates of accidental pediatric exposure (when a child accidentally takes the medicine) linked with the tablet form. If you are currently taking Suboxone Tablets, continue taking your medication and ask your doctor about how to transition to Suboxone Film. . . ."

b. "Dear Healthcare Professional . . . As we continue to work together to improve the health and well-being of opioid-dependent individuals, we would like to personally inform you about an important medication update . . . . The decision to discontinue Suboxone Tablets was based on accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone [film] compared with the tablet form . . . . We remain committed to supporting you with updated information and resources to ensure you have the tools you need to educate and transition your patients to Suboxone Film . . . . We thank you for your continued support of [Indivior] as we uphold our commitment to patients and the safety of the public."

[11] *Determination that SUBOXONE (Buprenorphine Hydrochloride and Naloxone Hydrochloride) Sublingual Tablets, 2 Milligrams/0.5 Milligrams and 8 Milligrams/2 Milligrams, Were Not Withdrawn From Sale For Reasons of Safety or Effectiveness*, 78 FR 34108 (June 6, 2013).

92. On or about December 4, 2012, the lead researcher from one of Indivior's contractors that had reviewed and analyzed notes of telephone calls to poison control centers emailed fellow researchers, stating that by using the research to supposedly justify discontinuing Suboxone tablet, Indivior "played us as a pawn and continues to do so. They are smart people, and they are playing a Machiavellian game."

H. Indivior Holds ANDA Approvals Hostage and Files a Sham Citizen Petition with the FDA.

93. To give itself more time to switch the market from Suboxone tablets to film, Indivior used additional anticompetitive tactics to delay the FDA's approval of competitors' ANDAs for generic Suboxone tablets. Indivior did this by sabotaging the process by which it and the generic manufacturers were required to finalize and submit to the FDA a shared REMS for Suboxone tablets.

94. On January 6, 2012, the FDA advised Indivior and the generic manufacturers that the generic Suboxone tablets would be subject to a Single Shared REMS (SSRS) program. FDA approval of the joint REMS was the final regulatory hurdle before FDA would approve generic Suboxone tablets. The FDA's Notification Letter advised all ANDA filers to contact Indivior to collaborate on the creation and implementation of an SSRS program. The Notification Letter also stated that the REMS should address pediatric exposures. The FDA mandated compliance by May 6, 2012. The deadline set by the FDA demonstrated the agency's expectation that Indivior's own previously-approved Suboxone REMS could be amended to add generic manufacturers in a relatively short time.

95. Although the FDA required the shared REMS, it did not contemplate that Indivior would use the requirement of a shared REMS to delay FDA approval of the generics. In fact, given that it had just approved Indivior's Suboxone tablet REMS in December 2011, the FDA

contemplated rapid development of a shared REMS. In addition to the FDA's recent approval of Indivior's Suboxone tablet REMS, the applicable statute regulating the REMS process provides that "[n]o holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection [Risk Evaluation and Mitigation Strategies, i.e., REMS] to block or delay approval of an application under section 355(b)(2) or (j) [21 U.S.C. § 355, regulating NDA and ANDA submissions] or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application." 21 U.S.C. § 355-1(f)(8). But the FDA underestimated Indivior's willingness to blatantly violate the statute regulating the REMS process in order to delay generic competition.

96. Indivior knew that if it participated in and did not sabotage the FDA-required process, the required joint REMS would quickly be completed, and the FDA would likely approve the generic Suboxone tablets for sale no later than May 2012. Indivior's problem was that, by May 2012, it could only successfully convert about 50% of its Suboxone unit sales from tablets to film. This would have left more than $500 million of Indivior's annual Suboxone tablet sales vulnerable to immediate loss to generic competition. Indivior therefore decided to sabotage the REMS process to further delay FDA approval of the generics and to buy more time to switch additional prescriptions from tablets to film.

97. Instead of coordinating its efforts and resources with ANDA applicants, Indivior unilaterally retained the services of the Researched Abuse, Diversion and Addiction-Related Surveillance System and Venebio Group, LLC to prepare a study on the risk of pediatric exposure to Suboxone tablets, but not Suboxone film. Indivior's goal in retaining these firms to conduct a study regarding only Suboxone tablets is obvious—Indivior was mobilizing its resources to ensure blocking, or at least delaying, ANDA applications.

98. Indivior knew that a joint REMS submission to the FDA was the final prerequisite to FDA approval of the pending Suboxone tablet ANDAs and realized that it was a required participant. Indivior thus sabotaged the joint process through unjustifiable and baseless delay tactics, flat refusals to participate, and pretextual conditions on participation—all nothing more than thin excuses intended to disguise its transparently anticompetitive intentions, in violation of 21 U.S.C. § 355-1(f)(8).

99. Indivior's sabotage of the joint process was documented in writing by the various generic manufacturers holding Suboxone tablet ANDAs. Those manufacturers were Actavis, Inc., Amneal Pharmaceuticals LLC, Ethypharm USA Corp., Mylan Inc., Roxane Laboratories Inc., Sandoz Inc., Sun Pharmaceuticals Industries, Ltd., and Teva Pharmaceuticals USA, Inc. One or more of those manufacturers reported to the FDA that Indivior:

a. merely feigned cooperation with the shared REMS development process;

b. refused to participate in meetings with the generic ANDA filers;

c. refused to discuss any substantive issues with the generic ANDA filers pertaining to the shared REMS when it did attend meetings;

d. placed unreasonable conditions on its cooperation with the shared REMS development process that it knew the ANDA filers could not agree to (such as to assume Indivior's tort liability by contract, which had nothing to do with the development of a joint REMS and would have caused the ANDA filers' liability insurers to disclaim coverage);

e. refused to sign the governing memorandum of understanding for the ANDA filers unless Indivior was given veto authority or super-majority vote for all issues relating to SSRS;

f. insisted that ANDA filers agree to pre-specified percentage of product liability claims regardless of fault;

g. refused to share information with the generic ANDA filers about the existing REMS program that was essential to the shared REMS development process—despite having entered into confidentiality agreements with ANDA filers;

h. raised a last-minute issue merely to cause still further delay just before a shared REMS was to be submitted to FDA in August 2012; and

i. stopped participating altogether in September 2012.

100. Indivior's sabotage of the shared REMS development process was intended to, and did, delay the FDA's approval of one or more Suboxone tablet ANDAs.

101. On May 6, 2012, and as a result of Indivior's actions, ANDA filers jointly requested a meeting with the FDA to discuss the delays created by Indivior. The FDA scheduled a meeting on June 18, 2012 and invited all ANDA filers and Indivior. During the meeting, after reviewing all written material and communications and hearing each party's oral presentation, the FDA agreed with the ANDA filers that Indivior was creating and causing delays to ANDA applications. To mitigate the conflict, the FDA asked the ANDA filers and Indivior to develop a new SSRS based upon the requirements set forth in the REMS Notification Letter, without using any of Indivior's existing information.

102. Indivior advised the FDA at the meeting that it would cooperate with the ANDA filers to develop this new SSRS, which Indivior knew was necessary for generic manufacturers to obtain approval of their respective ANDAs. But Indivior had an ulterior motive for participating in the new SSRS process. Despite its supposed commitment to cooperate, Indivior's goal was solely to maintain its access to proprietary information regarding ANDA applicants' filing status, timing, and content of the proposed new SSRS. This is evident by Indivior's continued intransigence and delay tactics.

103. For example, in mid-August 2012, the ANDA filers filed the SSRS with the FDA as part of their respective applications. Indivior refused to submit the new SSRS with its own NDA. Instead, Indivior suddenly, and only two days before the scheduled submission of the REMS documents to the FDA, raised an issue regarding a prescriber outreach component of the

SSRS involving the use of a field force, arguing that the generic manufacturers had omitted an important element of the REMS. This was yet another element in Indivior's overall campaign to sabotage and delay FDA approval of generic Suboxone tablets.

104. But, the *coup de grâce* came when Indivior used the final arrow in its quiver: filing a sham citizen petition with the FDA—a shot it perfectly timed based on information it received through the REMS process about the expected approval date of its competitors' applications.

105. After generic Suboxone tablet ANDA filers submitted a shared REMS of their own to the FDA in August 2012, Indivior knew that the FDA would likely accept the generics-only shared REMS, as submitted or with modification, and then quickly approve one or more generic Suboxone tablet ANDAs. But Indivior needed still more time to finalize and maximize its profits from its anticompetitive product-hopping scheme. By September 2012, Indivior still had converted only about 70% of the Suboxone unit sales from tablets to film. This left a still-hefty $300 million of Indivior's annual Suboxone revenue vulnerable to imminent loss to generic competition.

106. Indivior therefore implemented yet another anticompetitive delay tactic. On September 25, 2012—when Indivior knew that FDA approval of generic Suboxone tablets was imminent—Indivior announced its intent to permanently withdraw Suboxone tablets from the market for purported public safety reasons, and also filed an objectively baseless citizen petition with the FDA. Indivior had failed to disclose any of these so-called safety issues to the generic manufacturers during the REMS negotiations. After ten years on the market, and just as the FDA was ready to finally approve generic Suboxone tablets, Indivior suddenly and conveniently

"discovered" a safety issue so severe that it purportedly required the removal of Suboxone tablets from the United States market within the next six months.

107. Although the claims in Indivior's petition were wholly devoid of merit, the FDA could not approve the pending generic Suboxone tablet ANDAs without assuring itself that Indivior's petition was baseless, which the FDA did on February 22, 2013. During that five-month delay, however, Indivior reaped $400 million in additional Suboxone sales.

108. Indivior's petition was based entirely on the false "safety story." The petition asked the FDA to withhold approval of generic Suboxone tablet ANDAs unless: (1) the ANDA contained a targeted pediatric exposure education program; and (2) the ANDA product had child-resistant unit-dose packaging. Indivior's petition also asked that the FDA refrain from approving any generic Suboxone tablet ANDA until it determined whether Indivior discontinued the Suboxone brand tablet for safety reasons. Indivior claimed it would cease distribution of Suboxone tablets on March 18, 2013.

109. Indivior's petition referenced a new, five-page version of the executive summary, which Indivior's executives had participated in altering, but kept dated September 14, 2012, concealing the fact that it was altered from the version they originally cited for discontinuing Suboxone tablets. The alterations included deleting the statement that "any results related to the original packaging should be interpreted with considerable caution," and adding baseless conclusions.

110. Indivior did not even believe its own words that it put into its citizen petition. On August 30, 2012—just over three weeks before Indivior submitted its citizen petition on September 25, 2012—Indivior represented to the FDA in a combined REMS assessment that the tablet REMS was successful and needed no further changes. Indivior's statements to the

contrary in its citizen petition were not only false, but Indivior knew them to be false when it made them.

111. Indivior's petition also ignored the FDA's previously stated positions regarding unit-dose packaging. Indivior knew from a letter the FDA wrote to it in March 2010 that the FDA had long since concluded that, because of the high percentage of patients who took Suboxone in divided daily doses, unit-dose packaging did not ameliorate, and might even exacerbate, the known incidence of accidental pediatric buprenorphine exposure: "Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial doses that are neither in the child-resistant pouch nor in a child-resistant medication bottle[.]"

112. On February 22, 2013, the FDA denied Indivior's petition in its entirety. In rejecting Indivior's requests that ANDA filers be required to establish additional "education initiatives" (which were not a part of its own approved REMS) and market generic Suboxone products in unit-dose packaging, the FDA explained: (1) the data did not support Indivior's conclusion that its optional "educational interventions" were the cause of decreased pediatric exposures; and (2) the data did not support Indivior's purported concerns regarding "unit-dose packaging" because, among other things, the vast majority of pediatric exposure incidents came from *single or partial* doses of Suboxone—exposures that would not be affected or deterred at all by a unit-dose packaging requirement.

113. Even the FDA recognized and exposed the pretextual nature of Indivior's petition. The FDA observed:

> Since approval of the SUBOXONE film REMS in 2010 (and sub-sequent approval of the same REMS for SUBOXONE and SUBUTEX tablets in 2011), Indivior has not proposed any revisions to the REMS for these products to further address the risk of accidental pediatric exposure. In its August 30, 2012,

> combined REMS assessment for these products, which contained poison control center data and information gathered from surveys of patients and prescribers through that time, Indivior stated that the REMS for SUBOXONE had been successfully implemented and that it was not proposing any changes.

The FDA further added, "[t]he timing of Indivior's September 2012 announcement that it would discontinue marketing of the tablet product because of pediatric exposure issues, given its close alignment with the period in which generic competition for this product was expected to begin, cannot be ignored."

114. As to another of Indivior's key arguments that federal regulations prohibited the FDA from approving generic Suboxone tablets without first determining whether Indivior had withdrawn Suboxone from the market for safety or efficacy reasons, the FDA had a simple answer: *Indivior had not withdrawn the tablets from the market.* The FDA noted that Indivior declared its *intention* to withdraw from the market, but its products were still being shipped and sold, therefore the FDA was not obligated to make "[a] determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons may be made by the agency at any time after the drug has been voluntarily withdrawn from sale, but must be made: Prior to approving an abbreviated new drug application that refers to the listed drug." 21 C.F.R. 314.161(a)(1). The FDA then affirmatively stated that withdrawal of the Suboxone tablets was not necessary for reasons of safety.

115. On the same day that the FDA issued its scorching denial of Indivior's sham citizen petition, it granted the generic pharmaceutical companies' ANDA applications. But the damage was done.

116. The FDA alerted the FTC to Indivior's conduct. The FTC subsequently sued Indivior for its product hopping and abuse of the citizen petition process, alleging that in "September 2012, Indivior submitted a citizen petition requesting that the FDA reject any

generic Suboxone tablet applications or subject them to additional requirements because it knew doing so could delay approval of generics while the FDA reviewed it. The petition misrepresented a study that Indivior had commissioned and falsely claimed that there was evidence that the packaging of Suboxone Film reduced the risk of pediatric exposures." In recent remarks, the FTC has described Indivior's abuse of the citizen petition as a text book example of a sham petition used to extend a drug monopoly: "In July 2019, the Commission settled allegations that the pharmaceutical company Reckitt Benckiser maintained a monopoly in the market for certain opioid addiction treatments. Reckitt did so both by abusing the FDA citizens' petition process and by engaging in a broader 'product hopping' strategy that allowed it to thwart the entry of lower-cost generic drugs."[12] As the FTC's eventual action on Indivior's petition confirmed, there was no objective scientific, medical, or clinical basis for the petition. Reckitt Benckiser Group plc agreed to pay $50 million, and Indivior Inc. agreed to pay an addition $10 million, to settle FTC charges.

117. By the time generic manufacturers began selling generic Suboxone tablets in late February 2013, Indivior's anticompetitive tactics had almost entirely destroyed the prescription base for Suboxone tablets. Some 85% of Suboxone prescriptions were already being written for the film version of Suboxone.

118. Defendants' conduct has fueled a series of litigation against them, including:

a. the FTC action described above;

b. Direct Purchaser Plaintiffs and End-Payor Plaintiffs initiated several class-action complaints against Indivior in June 2013, alleging anticompetitive behavior with respect to its marketing and sale of Suboxone.

[12] U.S. Fed. Trade Comm'n, "The FTC's Ongoing Efforts to Promote Competition and Choice in Our Health Care System," Jan. 16, 2020, https://www.ftc.gov/system/files/documents/public_statements/1562909/csw_remarks_-_cahc_0.pdf.

c. Amneal Pharmaceuticals LLC, a generic manufacturer and competitor of Indivior, filed a complaint on December 23, 2015, regarding Indivior's anticompetitive conduct surrounding Suboxone; and

d. Thirty-six Attorneys General initiated a lawsuit against Indivior and MonoSol on September 22, 2016.

119. Defendants' conduct has also culminated in a number of criminal indictments and guilty pleas:

a. In April 2019, Reckitt Benckiser Group plc paid $1.4 billion to end criminal and civil investigations into its Suboxone marketing practices in the decade prior to the demerger with Indivior Inc. (known until December 2014 as Reckitt Benckiser Pharmaceuticals Inc.).[13]

b. On April 9, 2019, a federal grand jury in the Western District of Virginia indicted Indivior plc and Indivior Inc. on charges of health care fraud, wire fraud, mail fraud, and conspiracy, in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of Suboxone film and/or Suboxone tablets by certain physicians.

c. On June 30, 2020, former Indivior Chief Executive Officer Shaun Thaxter pleaded guilty in Virginia federal court to a misdemeanor for failing to prevent the company from giving misleading safety statistics about how often children were accidentally poisoned by the drug to Massachusetts officials as part of a marketing campaign for Suboxone film. The misleading statistics made it seem safer than comparable treatments in pill form, and Mr. Thaxter failed to correct the record at the time.

d. On July 24, 2020, Indivior Solutions Inc. pleaded guilty to a one-count criminal information based on this same Suboxone fraud Scheme. On that same date, Indivior entered into a $600 million civil settlement agreement with the DOJ regarding allegations that it submitted false claims to federal and state government Medicare and Medicaid agencies as a result of the Suboxone fraud Scheme. Indivior's settlement with the DOJ included an extraordinary requirement that Indivior Inc. completely disband its Suboxone sales force and never reinstate it. Indivior also entered into a $10 million civil settlement with the FTC, resolving claims that it engaged in illegal monopolization and anticompetitive conduct in violation of the

[13] As the DOJ announced, "The resolution—the largest recovery by the United States in a case concerning an opioid drug—includes the forfeiture of proceeds totaling $647 million, civil settlements with the federal government and the states totaling $700 million, and an administrative resolution with the Federal Trade Commission for $50 million." U.S. Dep't of Justice, "Justice Department Obtains $1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History," July 11, 2019, https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case.

Federal Trade Commission Act, 15 U.S.C. § 53(b). Together with the $1.4 billion resolution with Reckitt Benckiser Group plc, the DOJ's total resolution relating to the marketing of Suboxone is more than $2 billion— "the largest-ever resolution in a case brought by the Department of Justice involving an opioid drug."[14]

e. On August 31, 2020, former Global Medical Director of Reckitt Benckiser Pharmaceuticals Inc. and later Chief Medical Officer of Indivior plc, Timothy Baxter, pleaded guilty in Virginia federal court to a misdemeanor in violation of 21 U.S.C. §§ 331(a), 333(a)(1), 352(a) for causing "the introduction and delivery for introduction into interstate commerce of Suboxone Film, a drug that was misbranded in that the drug's labeling was false and misleading."[15]

120. Defendants also filed baseless patent litigation against generic film competitors as part of their anticompetitive strategy. MonoSol owned the relevant film patent and agreed with Indivior to continue to file new patent applications so that Defendants could file successive lawsuits against generic film competitors in order to improperly extend Indivior's monopoly power. Defendants exploited patent prosecution procedure, which enabled them to keep filing successive patents from the same application. Once they had been defeated in the first patent litigation, Defendants were able to file successive cases against generic competitors in order to maintain their monopoly power. For example, MonoSol and Indivior filed an initial patent infringement suit asserting infringement of one or more sublingual patents. After losing that case because the court determined that the generic Suboxone film would not infringe the MonoSol patent asserted there, MonoSol and Indivior obtained new patents, and asserted a new patent (in the same family) against other generic competitors. Defendants collectively and improperly leveraged their patents, including invalid patents, to develop marketing and legal

[14] U.S. Dep't of Justice, "Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay $600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution," July 24, 2020, https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.

[15] *See United States v. Baxter*, No. 1:20-cr-00032-JPJ-PMS (W.D. Va. Aug. 31, 2020) (ECF No. 1 at p. 10 ¶ 33).

strategies that enabled Indivior to manipulate the market for Suboxone products and decrease competition for Suboxone film.

121. Defendants took each and every one of these steps in their fraudulent Suboxone Scheme with a single goal in mind: to manipulate the market by destroying the prescription base for Suboxone tablets before generic tablets entered the marketplace, thereby preventing generic Suboxone tablets from effectively competing through the most efficient means available—automatic generic substitution at the pharmacy counter. Defendants then solidified their film product monopoly through baseless litigation against film product competitors.

I. Defendants' Suboxone Scheme Constitutes Racketeering.

122. Indivior designed and coordinated the multifaceted and fraudulent Suboxone Scheme intended to charge and maintain inflated prices for Suboxone, the Suboxone market, and to defraud payors like Humana.

123. In so doing, Indivior conducted the activities of an association-in-fact enterprise (the "Suboxone Enterprise") consisting of the Indivior Defendants and MonoSol through a pattern of racketeering activity, including mail and wire fraud.

124. Between 2006 and the date of its criminal indictment, Indivior, with the intent to defraud, devised and willfully participated with MonoSol, and with knowledge of its fraudulent nature, in the scheme and artifice to defraud and obtain money and property by materially false and fraudulent pretenses, representations, and promises described in the factual allegations of this Complaint.

125. Including, but not limited to on the dates identified below, Indivior and MonoSol caused to be delivered by mail and private or commercial interstate carrier according to the direction thereon, the named matter and thing, namely, marketing visual aids containing materially false and fraudulent representations that Suboxone film is safer and less susceptible to

misuse, abuse, diversion, and accidental child exposure than other, similar drugs, including misleading text, graphics, and charts, to an Indivior sales representative in Roanoke, Virginia, who promoted Suboxone film to physicians, pharmacists, and others in locations including Blacksburg, Cedar Bluff, Charlottesville, Christiansburg, Danville, Galax, Lynchburg, Roanoke, Salem, Staunton, Willis, and Wytheville, Virginia.

126. **Mail Fraud Date Examples**

a. February 6, 2012

b. January 4, 2013

c. March 21, 2013

d. August 19, 2013

127. All of these mailings, and many similar mailings, were made in violation of Title 18, United States Code, Sections 2 and 1341.

128. Including, but not limited to on the dates identified below, Indivior and MonoSol, caused to be transmitted by wire communication or radio communication in interstate and foreign commerce, writings, signs, signals, pictures, and sounds, namely, reports of clinical liaisons falsely and fraudulently representing to physicians, pharmacists, and other health care providers that Suboxone film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, transmitted from Florida and New Jersey to locations in Virginia, and referrals of prospective patients to physicians, transmitted from Pennsylvania to locations in Virginia, as described below.

129. **Wire Fraud Date Examples**

	DATE	**ITEM**
a.	April 30, 2010	Referral to Physician
b.	October 9, 2010	Activity Report with Model Safety Claims

c.	October 24, 2010	Activity Report with Model Safety Claims
d.	November 29, 2010	Activity Report with Model Safety Claims
e.	June 1, 2011	Referral to Physician
f.	July 8, 2011	Activity Report with Model Safety Claims
g.	September 2, 2011	Referral to Physician
h.	October 6, 2011	Referral to Physician (1 of 2 on this date)
i.	October 6, 2011	Referral to Physician (2 of 2 on this date)
j.	May 1, 2012	Referral to Physician
k.	April 12, 2013	Referral to Physician
l.	April 26, 2013	Referral to Physician
m.	December 13, 2013	Referral to Physician
n.	November 3, 2014	Referral to Physician
o.	March 10, 2015	Referral to Physician
p.	March 13, 2015	Referral to Physician
q.	March 18, 2015	Referral to Physician
r.	April 27, 2015	Referral to Physician
s.	May 26, 2015	Referral to Physician (1 of 2 on this date)
t.	May 26, 2015	Referral to Physician (2 of 2 on this date)
u.	June 18, 2015	Referral to Physician
v.	July 8, 2015	Referral to Physician

130. In addition, numerous email transmissions containing false information were used as part of the Scheme. For example, on October 16, 2012, Indivior's Medical Manager sent an email to a MassHealth pharmacy director containing altered, inaccurate pediatric exposure data for Suboxone film, Suboxone tablet, and buprenorphine-only tablets, making it appear as though Suboxone film had the lowest rate of pediatric exposure in Massachusetts when, in fact,

buprenorphine-only tablets did. Indivior's Medical Manager sent Indivior's Medical Director email chains showing that she had altered the data and stating that she sent the altered data to "help us get some movement in Mass" on Medicaid coverage of Suboxone film. Upon receiving additional data unfavorable to Suboxone film, Indivior's Medical Manager declined to provide it to Medicaid personnel, and told Indivior Government Managers that her rationale for withholding the unfavorable information from Medicaid personnel was, "don't ask, don't tell."

131. On April 18, 2013, Indivior's Government Manager and Medical Manager sent an email to Kentucky Department for Medicaid Services commissioner and other officials stating that compared to Suboxone film, the tablet form "increases the risk of diversion with adult recipients because it can be crushed and snorted. . . . [S]ometimes leadership requires you to make a decision locally to protect the residents of the State of Kentucky that you serve. You've chosen not to . . ."

132. These wire communications, and many similar wire communications, were made in violation of Title 18, United States Code, Sections 2 and 1343.

133. Indivior and MonoSol used thousands of mail and interstate wire communications to create and manage their Suboxone Scheme, which involved the nationwide distribution of Suboxone film. Moreover, the massive, nationwide false "safety story" marketing scheme described above involved numerous acts of mail and wire fraud. The predicate acts of mail and wire fraud described above, as well as in the Indivior indictment, constituted a pattern of racketeering activity.

134. Indivior's racketeering activity damaged Humana. Humana paid hundreds of millions of dollars for Suboxone film, as well as higher prices for Suboxone tablets, due to the mail and wire fraud, and pattern of racketeering activity alleged herein.

J. Indivior Officers, Directors, Sales Representatives and Other Employees Played Key Roles in the Suboxone Scheme.

135. Indivior officers and directors played key roles in the Suboxone film fraud Scheme. Shaun Thaxter was the Chief Executive Officer of Indivior plc. Thaxter pleaded guilty to the Introduction of Misbranded Drugs in Interstate Commerce as part of the Scheme, violating 21 U.S.C. §§ 331(a)(1), and 352(a), as set forth in the criminal information incorporated by reference and attached as Exhibit 3 to this Complaint.

136. Timothy Baxter was the Global Medical Director for Indivior plc and had responsibility for and authority over Indivior Solutions, Inc.'s medical affairs. Baxter also pleaded guilty to the Introduction of Misbranded Drugs in Interstate Commerce as part of the Scheme, violating 21 U.S.C. §§ 331(a)(1), and 352(a), as set forth in the criminal information incorporated by reference and attached as Exhibit 4 to this Complaint.

137. Many other Indivior employees and sales representatives have knowledge of the facts related to the allegations in this Complaint. Based upon information and belief, those employees and sales representatives include, but are not limited to:

a. Ana Farr (aka Ana Craig): State College, Pennsylvania;

b. Scott Daniel: Staffordsville, Kentucky;

c. Jaime Neil: Lexington, Kentucky;

d. Joe Hall: Greeneville, Tennessee;

e. Clint Gagnon: Roanoke, Virginia;

f. Mary Bhaskar: Pittsburgh, Pennsylvania;

g. Teri Turconi: Pittsburgh, Pennsylvania;

h. Melanie Miller: Pittsburgh, Pennsylvania;

i. Mathew Holland: McCordsville, Indiana;

j. Scott Norman: Chicago, Illinois;

k. Gina Reed: Indianapolis, Indiana;

l. Lori Davis: Bridgeville, Pennsylvania;

m. Daphne Atkins: Richmond, Virginia;

n. Lori Eaton: Lake Grove, New York; and

o. Andrea "Andie" Hall: Greenville, Tennessee.

K. Fraudulent Concealment of the Suboxone Scheme.

138. Defendants actively concealed the existence of their illegal Suboxone Scheme. Indeed, it took the DOJ years to investigate, uncover, indict and prosecute Indivior. The DOJ indictment, as well as the emails, phone conversations, and documents identified in the indictment, revealed the fraudulent Suboxone Scheme.

139. Until the DOJ indictment and entry of guilty pleas, Defendants continued to affirmatively and overtly conceal their fraud through affirmative misrepresentations about their film product's safety and efficacy, and through aggressive denials of any misrepresentations. For example:

a. Defendants claimed that Suboxone film out-performed other products such as generic tablets, because of Suboxone film's "superior qualities" and unique dosage form.

b. As described throughout this Complaint, Defendants repeatedly lied about the safety of their Suboxone film product when, in fact, the tablet version that they were pulling off the market was safer.

c. Defendants continued to publicly and overtly claim that there was no basis for the claims that they lied about the safety risks of both Suboxone tablets and film: "The States also levy the false accusation that Indivior 'was aware that its assertion of pediatric safety concerns regarding the tablet formulation were unfounded.'"[16]

d. In an open letter from the Indivior Chairman of the Board, Indivior rebuked the government for bringing criminal charges against the company. The Chairman explained that "[t]he Indivior Board of Directors, including through a special

[16] Indivior Inc.'s Motion to Dismiss at 6, *Wisconsin, et al. v. Indivior Inc. et al.*, No. 2:16-cv-5073-MSG (E.D. Pa. Dec. 12, 2016), ECF No. 138-1.

> committee of the board that [he] chaired, [] investigated the department's allegations, and the board believes they are flat wrong."

140. Due to Defendants' fraudulent concealment, Humana could not have discovered and remained unaware of the Suboxone Scheme, including the instances of mail and wire fraud, until the DOJ filed its indictment on April 9, 2019. The indictment set forth the internal statements of Indivior's top executives discussing their fraudulent Suboxone Scheme and plan, which belied Indivior's indignant denials of any kind of wrongdoing.

L. Defendants' Suboxone Scheme Was Intended To, And Did, Harm Competition.

141. Indivior's motive to injure competition is illustrated by its willingness to sacrifice short-term profits as part of its product-hopping strategy. Indivior's decisions to incur the extra costs (and suffer the revenue losses) associated with the change in Suboxone's dosage form from tablets to film and the discontinuation of Suboxone tablets were economically rational only because those changes had the exclusionary effect of suppressing generic competition. But for the impact on generic competition, Indivior would not have invested the resources necessary to develop the inferior Suboxone film product, and destroy the prescription base for Suboxone tablets, because it would have been economically irrational to do so.

142. Indivior's unjustifiable delay and refusal to cooperate with the generic ANDA filers in the joint REMS process mandated by the FDA, in violation of 21 U.S.C. § 355-1(f)(8), directly prevented the generic ANDA filers from obtaining FDA approval. But for Indivior's unlawful conduct, the FDA would have approved one or more generic Suboxone tablets no later than May 2012.

143. Indivior's baseless, sham citizen petition further delayed FDA approval of generic Suboxone tablets. But for Indivior's sham filing, the FDA would have approved one or more generic Suboxone tablets no later than September 2012.

144. To the extent it is even permitted to do so, Indivior cannot justify its Scheme by pointing to any offsetting consumer benefit. The enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Suboxone) outweigh any cognizable, non-pretextual procompetitive justifications Indivior could possibly offer.

145. Any justifications Indivior could offer for its Scheme are, in fact, pretexts. And, whatever justifications Indivior may offer, Indivior did not need to engage in the conduct challenged in this lawsuit to achieve them.

146. If Indivior were simply interested in introducing a new Suboxone film product to compete on the merits with Suboxone tablets, it could have done so without taking the additional, affirmative steps described herein to: (a) fraudulently market its Suboxone film and falsely disparage its Suboxone tablet; (b) delay the market entry of less-expensive generic versions of Suboxone tablets; (c) interfere with the normal competition that routinely occurs between branded products and their generic counterparts as contemplated by the Hatch-Waxman Act; and (d) destroy the prescription base for Suboxone tablets.

147. If Indivior were simply and solely interested in modifying the container closure system for Suboxone in the United States to contain a unit-dose packaging feature, it could have done so, as it has done in several other countries since 2005, without reformulating Suboxone's dosage form into a film and thereby destroying the automatic substitutability of Suboxone tablets.

148. As a result of its illegal Scheme, Indivior: (1) illegally maintained and extended its monopoly in the market for Suboxone; (2) fixed, raised, maintained, and/or stabilized the price of Suboxone at supra-competitive levels; and (3) overcharged Humana by hundreds of

millions of dollars by depriving Humana of the benefits of competition from cheaper generic versions of Suboxone.

149. Indivior maintained its monopoly power, as alleged more fully below, through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident. Neither Indivior's Scheme as a whole, nor any of its constituent parts, constituted competition on the merits.

150. Indivior violated the state statutes and common law enumerated below through its overarching Scheme to improperly maintain and extend its monopoly power by foreclosing or delaying competition from lower-priced generic versions of Suboxone.

M. Effects on Competition and Antitrust Damages to Humana.

151. Indivior's fraud and overarching anticompetitive Scheme impaired and delayed the sale of generic Suboxone tablets in the United States, and unlawfully enabled Indivior to sell Suboxone at artificially inflated prices. But for Indivior's illegal conduct, generic competitors would have been able to compete, unimpeded, with generic versions of Suboxone tablets.

152. If manufacturers of generic Suboxone tablets had been able to enter the marketplace and effectively compete with Indivior earlier or without Indivior's having switched the market to Suboxone film, as set forth above, Humana would have: (1) substituted lower-priced generic Suboxone tablets for the higher-priced brand-name Suboxone tablets for some or all of their Suboxone requirements; (2) paid a lower price for their generic Suboxone products, sooner; and/or (3) paid lower prices for some or all of their remaining branded Suboxone purchases.

153. Defendants' Suboxone Scheme, however, has impaired and delayed the FDA approval of the generic products, and deprived the manufacturers of generic Suboxone tablets of

the cost- efficient means of distribution, thus artificially limiting the pool of potential generic tablet prescriptions to a small fraction of the total Suboxone prescriptions.

154. Suboxone film was created for the sole purpose of illegal monopolization of the Suboxone market. Humana would have never paid for Suboxone film but for Indivior's anticompetitive scheme.

155. As a result of Indivior's anticompetitive scheme, however, when generic Suboxone tablets finally entered the market, Indivior had converted some 85% of the unit sales from tablets to the non-substitutable film. Consequently, a fraction of Indivior's annual sales of Suboxone were in tablet form and thus available for automatic generic substitution.

156. Absent the product hop and the coercion of the market from tablet to film, generic tablets would have captured a far greater percentage of the market regardless of when they entered the market.

157. Absent Indivior's improper, deceptive, coercive and delaying tactics, Suboxone film would have captured, at best, only a very small percentage of the Suboxone market, and generic tablets would have captured most of the market quickly after entering.

158. Defendants' improper Suboxone Scheme involved a series of price increases for Suboxone film and Suboxone branded tablets which would not have occurred but for Indivior's improper conduct. Had generic tablets entered earlier, absent Indivior's improper conduct, not only would generic tablets have captured greater market share (because branded Suboxone tablets would have had a greater share of the Suboxone market, which would have eventually been converted to generics), but also: (a) branded Suboxone tablet prices would have been substantially lower; (b) generic Suboxone tablet prices would have been substantially lower; and (c) Suboxone film prices would have been lower.

159. Even if certain conversions to the film were "legitimate," the price of the film was still artificially inflated. The film overcharge did not end with generic entry of the tablets and will continue forward into the future.

160. General economic principles recognize that any overcharge at a higher level of distribution generally results in higher prices at every level below. Moreover, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors like Humana. Wholesalers and retailers passed on the inflated prices of Suboxone to Humana. The impairment and delay of generic competition at the direct-purchaser level similarly injured Humana, who was equally denied the opportunity to purchase cheaper Suboxone.

161. During the relevant period, Humana purchased substantial amounts of Suboxone. Humana's Suboxone purchases were made according to the wholesale cost that Indivior set and controlled. Humana purchased Suboxone from 2010 to 2018 and also from other specialty pharmacies that fulfilled prescriptions for Humana's members located in all 50 states, the District of Columbia, and Puerto Rico.

162. As a result of Defendants' illegal conduct as alleged herein, Humana was compelled to pay, and did pay, artificially inflated prices for its Suboxone requirements. Humana paid prices for Suboxone that were substantially greater than the prices it would have paid absent the illegal conduct alleged herein.

163. As a consequence, Humana has sustained substantial losses and damage to its business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

N. Effect on Interstate and Intrastate Commerce.

164. At all material times, Suboxone, manufactured by MonoSol and sold by Indivior, was shipped across state lines and sold to customers located outside its state of manufacture.

165. During the relevant time period, in connection with the purchase and sale of Suboxone, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow of intrastate and interstate commerce.

166. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail and wires, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Indivior, as alleged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

167. Indivior's racketeering and anticompetitive conduct occurred in part in trade and commerce within the states set forth herein, and also had substantial intrastate effects in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Suboxone to end-payors inside each respective state. The foreclosure of generic Suboxone directly impacted and disrupted commerce for Humana, who was forced to pay supra-competitive prices in each state.

168. Before it was disbanded as a result of its criminal guilty plea, Indivior Solutions Inc.'s United States sales force engaged in fraudulent marketing activity in every state.

169. MonoSol manufactures all Suboxone film sold in interstate commerce throughout the United States. MonoSol's unlawful activities alleged in this Complaint have occurred in and have had a substantial effect on interstate commerce. MonoSol has received fixed payments as well as royalties associated with the sales of Suboxone film.

O. Monopoly Power.

170. At all relevant times, Indivior had monopoly power over Suboxone, because it had the power to raise and/or maintain the price of Suboxone at supra-competitive levels without losing so many sales as to make the supra-competitive price unprofitable.

171. To the extent that Humana is required to prove monopoly power circumstantially by first defining a relevant product market, Humana alleges that the relevant product market is all Suboxone products—i.e., Suboxone in all its forms and dosage strengths and the respective generic equivalents.

172. A small but significant, non-transitory price increase by Indivior to Suboxone would not have caused a significant loss of sales to other drugs or products used for the same purposes, with the exception of generic versions of Suboxone.

173. At competitive prices, Suboxone does not exhibit significant, positive cross-elasticity of demand with respect to price, with any opioid dependence treatment or other product other than generic versions of Suboxone.

34. Indivior needed to control only Suboxone and its generic equivalents, and no other products, in order to maintain the price of Suboxone profitably at supra-competitive prices. Only the market entry of a competing, generic version of Suboxone would render Indivior unable to profitably maintain supra-competitive prices for Suboxone.

174. Indivior also sold branded Suboxone substantially in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

175. At all relevant times, Suboxone was unique and not reasonably interchangeable with other therapies for the treatment of opioid addiction. Suboxone was unique in that it is an opioid replacement therapy. Suboxone was unique in that it is a maintenance therapy. Suboxone was unique in that it was the only FDA-approved opioid replacement maintenance therapy

(unlike methadone, which has never been formally approved by the FDA). Suboxone was unique in that it was the only opioid replacement maintenance therapy that was a Schedule III drug under the Controlled Substances Act and could be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000 (unlike methadone, which is a Schedule II drug, and must be administered in a clinic setting). Suboxone was unique in that it was the only opioid replacement maintenance therapy that was co-formulated with an opioid antagonist (naloxone) to deter abuse. Suboxone was unique in that it was the only opioid replacement maintenance therapy that was only a partial (as opposed to full) agonist of the μ-opioid receptor; thus, unlike methadone or other full agonists, Suboxone's unique properties created a "ceiling effect" that prevented larger doses of buprenorphine from producing greater agonist effects, protecting patients against death by respiratory depression or overdose. This property also afforded Suboxone a unique efficacy profile: unlike methadone, which is prescribed for a patient population suffering from severe forms of opioid addiction, Suboxone was suitable only for patients with mild to moderate forms of opioid addiction.

176. The relevant geographic market is the United States and its territories.

177. At all relevant times, Indivior enjoyed high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

178. On or about August 5, 2013, Indivior's Chief Executive Officer emailed Reckitt Benckiser Group plc's Chief Executive Officer and others, stating that Suboxone film's share of the market had grown to 69.1%, which was "almost enough to make you wonder when we will break through the 70% share barrier?" Reckitt Benckiser Group plc's Chief Executive Officer replied-all, "I agree, our US team has done a fantastic job of defending our film share thus far."

179. Indivior's own Annual Reports continually touted its monopolistic market share and its ability to retain its high market share. With respect to Suboxone film alone:

a. Suboxone film had a 64% market share by the end of 2012, up from 48% at the end of 2011;

b. Suboxone film exited 2013 with a 67% share of the United States buprenorphine market;

c. Suboxone film exited 2014 with a 58% share of the United States buprenorphine market, averaging 62% for the year;

d. In 2015, Suboxone film sustained market share in the United States on average of 59%;

e. In 2016, Suboxone film increased its average market share to 61%;

f. In 2017, Indivior maintained Suboxone film's "leading share position" at an average of 57% in the United States, "despite competition from lower priced generic options";

g. Suboxone film's market share only dropped slightly to 53% in 2018 "[d]espite continued competition from manufacturers of generic [Suboxone tablets] and the market impact of [a competitor's generic Suboxone film launch]";

h. In 2019, average market share was 32% for Suboxone film;

i. As of early March 2020, Suboxone branded products retain approximately 43% of the film market share and "the branded Suboxone[] has continued to retain significant market share."

180. The improper steps Defendants took to create prescriber preference for Suboxone film—and to remove buprenorphine/naloxone tablets as an acceptable alternative to the film—were successful in changing prescriber preferences and practices.

CLAIMS FOR RELIEF

COUNT I:

Violation of the RICO Act, 18 U.S.C. § 1962(c) (AGAINST THE INDIVIOR DEFENDANTS)

181. Humana hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

182. Indivior is a "person" within the meaning of 18 U.S.C. § 1961(3), that conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

183. The Suboxone Enterprise was an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Indivior and MonoSol — including their employees, and agents.

184. The Suboxone Enterprise was an ongoing organization that functioned as a continuing unit. The Suboxone Enterprise was created for and used as a tool to effectuate a pattern of racketeering activity. Each member of the Suboxone Enterprise played different roles in the Suboxone Scheme, is functionally distinct, and used their separate legal incorporation to facilitate the racketeering activity.

185. Indivior and MonoSol are alternatively each "persons" distinct from the Suboxone Enterprise.

186. Indivior established the Suboxone Enterprise to fraudulently increase its sales of Suboxone film and prevent or delay generic entry into the Suboxone market.

187. Indivior knew that their Suboxone Scheme violated federal and state laws.

188. False representations were made to Humana for payment over the wires or by mail.

189. The Suboxone Enterprise engaged in and affected interstate commerce because, among other things, it marketed, sold, purchased, or provided Suboxone film to thousands of individuals throughout the United States.

190. Indivior asserted control over the Suboxone Enterprise by designing and implementing the fraudulent Suboxone Scheme, including creating the joint venture with MonoSol, concocting the fabricated "safety story," and disseminating that false story nationwide through mail and wire fraud.

191. Indivior has conducted and participated in the affairs of the Suboxone Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), and 1952 (use of interstate facilities to conduct unlawful activity). The effect of Indivior's racketeering activity was to induce and increase sales of Suboxone film that otherwise would not have been made in the absence of the illegal conduct, to maintain or raise the price of Suboxone film to a higher level than it would have commanded in the absence of the illegal conduct, and to preclude or delay generic entry.

192. Humana suffered injuries when it reimbursed prescriptions for Suboxone that otherwise would not have been made and/or paid the higher prices that resulted from the illegal conduct.

193. Indivior's racketeering activities, as described above, directly injured Humana. By virtue of these violations of 18 U.S.C. § 1962(c), Indivior is jointly and severally liable to Humana for three times the damages Humana has sustained, plus the cost of this suit, including reasonable attorneys' fees.

194. Indivior participated in the affairs of the Suboxone Enterprise through a pattern of racketeering activity and has engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346;

d. Multiple instances of unlawful activity in violation of 18 U.S.C. §1952.

COUNT II:

Conspiracy to Violate the RICO Act, 18 U.S.C. § 1962(d)
(AGAINST ALL DEFENDANTS)

195. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

196. Title 18 U.S.C. § 1962(d) provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

197. Indivior violated 18 U.S.C. § 1962(d) by conspiring with MonoSol to violate 18 U.S.C. §1962(c). The object of this conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the Suboxone Enterprise described previously through a pattern of racketeering activity.

198. Indivior and its co-conspirator have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Humana of money.

199. The nature of the above-described Indivior's co-conspirator's acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring

to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

200. Indivior's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c) directly injured Humana in its business and property as set forth more fully above.

201. Indivior and its co-conspirator have sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346;

d. Multiple instances of unlawful activity in violation of 18 U.S.C. §1952.

COUNT III:

Fraud Under State Law
(AGAINST ALL DEFENDANTS)

202. Humana hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

203. Defendants' creation of the Suboxone film product was itself a fraud.

204. Indivior made, aided, abetted, counseled, commanded, induced, and procured others to make the materially false and fraudulent statements and representations described in detail above, including:

a. Representing to Humana, other health care providers, physicians, and pharmacists that Suboxone film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, and has other unsubstantiated effects such as weeding out drug seekers, making patients feel less like addicts, protecting physicians from being criminally prosecuted, and protecting office-based treatment of opioid addition/dependence from being banned; and

b. Producing and disseminating printed marketing materials representing that Suboxone film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, containing misleading text, graphics, and charts.

205. Indivior knew that the development and creation of its Suboxone film product was a fraud undertaken for the sole purpose of extending its monopolistic market share in the market for Suboxone.

206. Indivior knew that the statements and misrepresentations about the product were false, where Indivior had commissioned various reports that only confirmed the falsity of the statements and misrepresentations.

207. Humana reasonably relied on Indivior's statements and misrepresentations—not knowing they were false statements or misrepresentations—and included Suboxone film on its formularies. Humana rightfully relied on Indivior's false statements and misrepresentations.

208. It was the intent and object of Defendants' Scheme to fraudulently induce physicians to write prescriptions for Suboxone film, for pharmacists to fill prescriptions of Suboxone film, and for health care benefit programs like Humana to provide coverage of prescriptions for Suboxone film.

209. As a direct and proximate result of Defendants' fraud, Humana was injured.

210. Humana exercised reasonable diligence in investigating Indivior's conduct with respect to Suboxone film.

211. Despite Humana's diligence, Humana did not know and could not by reasonable diligence have discovered the facts constituting Indivior's fraud, Humana's cause of action for fraud, or even that Humana had been injured, until the publication of the April 9, 2019, federal indictment of Indivior for fraud. Defendants had planned and undertaken their fraudulent development of Suboxone film in secret such that the fraud was self-concealing, and Defendants thereafter affirmatively concealed that fraud with a continuous course of fraudulently concealing

conduct lasting at least until April 9, 2019. As a result, the facts making Defendants' development of Suboxone film fraudulent, and the facts rendering Humana's payment for Suboxone film an injury, were not reasonably knowable.

212. Prior to the publication of the Federal indictment of Indivior for fraud, Humana did not have notice of facts that would prompt a reasonably prudent person to investigate whether Defendants' development of Suboxone film had been fraudulent. Furthermore, even if a person in Humana's position had pursued a reasonably diligent investigation, such an investigation would not have produced knowledge or discovery of the facts constituting Indivior or MonoSol's fraud, Humana's cause of action for fraud, or even that Humana had been injured, that is, that Indivior and MonoSol's development of Suboxone film had been fraudulent.

213. Humana is entitled to recover damages, including punitive damages, against Defendants based on fraud in an amount to be determined at trial, but not less than 50 million dollars.

COUNT IV:

Monopolization and Monopolistic Scheme Under State Law
(AGAINST ALL INDIVIOR DEFENDANTS, EXCEPT RECKITT BENCKISER HEALTHCARE (UK) LTD.)

214. Humana hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

215. At all relevant times, Indivior's Suboxone products possessed over 50% market share and substantial market power (i.e., monopoly power) in the relevant market. Indivior possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

216. Through the overarching anticompetitive scheme, as alleged above, Indivior willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen.

217. It was Indivior's conscious objective to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

218. Indivior's scheme harmed competition, as alleged above.

219. There is and was no cognizable, non-pretextual procompetitive justification for Indivior's actions comprising the anticompetitive scheme that outweigh the scheme's harmful effects. Even if there were some conceivable justification that Indivior could assert, the scheme is and was broader than necessary to achieve such a purpose.

220. Indivior's conduct, as alleged herein, directly and proximately injured Humana.

221. By engaging in the foregoing conduct, Indivior has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following laws, where overcharges occurred:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Suboxone in Arizona;

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law, with respect to purchases of Suboxone in California;

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia;

d. Hawaii Code §§ 480, *et seq.*, with respect to purchases of Suboxone in Hawaii;

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Suboxone in Illinois;

f. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Suboxone in Iowa;

g. Kansas Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Suboxone in Kansas;

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine;

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Suboxone in Michigan;

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota;

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Suboxone in Mississippi;

l. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of Suboxone in Montana;

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada.

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Suboxone in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico;

q. N.Y. Gen. Bus. Law §§ 340, *et. seq.*, with respect to purchases of Suboxone in New York;

r. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina;

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Suboxone in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone in Oregon;

u. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Suboxone in Puerto Rico;

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Suboxone in Rhode Island;

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.,* with respect to purchases of Suboxone in South Dakota;

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Suboxone in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah, where Humana is a citizen of Utah;

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont;

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Suboxone in West Virginia;

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin.

COUNT V:

Attempted Monopolization Under State Law
(AGAINST ALL INDIVIOR DEFENDANTS, EXCEPT RECKITT BENCKISER HEALTHCARE (UK) LTD.)

222. Humana hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

223. Indivior, through its anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Indivior's conscious objective to control prices and exclude competition in the relevant market.

224. The natural, intended, and foreseeable consequence of Indivior's anticompetitive scheme was to control prices and exclude competition in the relevant market.

225. There is a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Indivior will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

226. Indivior's conduct, as alleged herein, directly and proximately injured Humana with respect to Humana's indirect purchases of Suboxone.

227. By engaging in the foregoing conduct, Indivior has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following laws, where overcharges occurred:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Suboxone in Arizona;

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law, with respect to purchases of Suboxone in California;

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Suboxone in the District of Columbia;

d. Hawaii Code §§ 480, *et seq.*, with respect to purchases of Suboxone in Hawaii;

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Suboxone in Illinois;

f. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Suboxone in Iowa;

g. Kansas Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Suboxone in Kansas;

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Suboxone in Maine;

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Suboxone in Michigan;

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Suboxone in Minnesota;

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Suboxone in Mississippi;

l. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of Suboxone in Montana;

m. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Suboxone in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Suboxone in Nevada.

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*, with respect to purchases of Suboxone in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Suboxone in New Mexico;

q. N.Y. Gen. Bus. Law §§ 340, *et. seq.*, with respect to purchases of Suboxone in New York;

r. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Suboxone in North Carolina;

s. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Suboxone in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Suboxone in Oregon;

u. 10 L.P.R.A. §§ 257, *et seq.*, with respect to purchases of Suboxone in Puerto Rico;

v. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to purchases of Suboxone in Rhode Island;

w. S.D. Codified Laws §§ 37-1-3.2, *et seq.,* with respect to purchases of Suboxone in South Dakota;

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Suboxone in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

y. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Suboxone in Utah, where Humana is a citizen of Utah;

z. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Suboxone in Vermont;

aa. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Suboxone in West Virginia;

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Suboxone in Wisconsin.

COUNT VI:

Unfair and Deceptive Trade Practices Under State Law
(AGAINST ALL DEFENDANTS)

228. Humana hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

229. Indivior and MonoSol engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Indivior and MonoSol's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Humana was deprived of the opportunity to purchase Suboxone at prices restrained by competition and forced to pay

artificially inflated prices. There was a gross disparity between the price that Humana paid for Suboxone and the value received, given that more cheaply priced Suboxone should have been available, and would have been available, absent Indivior and MonoSol's illegal conduct.

230. By engaging in the foregoing conduct, Indivior and MonoSol have engaged in in unfair competition or deceptive acts and practices in violation of the following laws, where overcharges occurred:

a. Ariz. Code §§ 44-1522, *et seq.*, with respect to purchases of Suboxone in Arizona;

b. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases of Suboxone in Arkansas.

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Suboxone in California;

d. Colo. Rev. Stat § 6-1-105, *et seq.*, with respect to purchases of Suboxone in Colorado;

e. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases of Suboxone in the District of Columbia;

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Suboxone in Florida;

g. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Suboxone in Idaho;

h. 815 ILCS §§ 505/1, *et seq.*, with respect to purchases of Suboxone in Illinois;

i. Ind. Code §§ 24-5-0.5-1, *et seq.*, with respect to purchases of Suboxone in Indiana;

a. Kan. Stat. §§ 50-623, *et seq.*, with respect to purchases of Suboxone in Kansas;

j. La. Rev. Stat. Ann. § 51:1401, *et seq.*, with respect to purchases of Suboxone in Louisiana;

k. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to purchases of Suboxone in Maine;

l. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Suboxone in Massachusetts;

m. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases of Suboxone in Michigan;

n. Minn. Stat. § 325D.43, *et. seq.*, Minn. Stat. § 325F.69, *et seq.*, and Minn. Stat. § 8.31, et seq., with respect to purchases of Suboxone in Minnesota;

o. Miss. Code. Ann. § 75-24-1, *et seq.*, with respect to purchases of Suboxone in Mississippi

p. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases of Suboxone in Missouri;

q. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Suboxone in Nebraska;

r. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of Suboxone in Nevada;

s. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of Suboxone in New Hampshire;

t. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases of Suboxone in New Mexico;

u. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Suboxone in New York;

v. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Suboxone in North Carolina;

w. N.D. Cent. Code § 51-15-01, *et seq.*, with respect to purchases of Suboxone in North Dakota;

x. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Suboxone in Oregon;

y. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Suboxone in Pennsylvania;

z. S.C. Stat. Ann. § 39-5-10, *et seq.*, for purchases of Suboxone in South Carolina;

aa. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases of Suboxone in South Dakota;

bb. Utah Code §§ 13-11-1, *et seq.*, with respect to purchases of Suboxone in Utah;

cc. 9 Vt. § 2451, *et seq.*, with respect to purchases of Suboxone in Vermont;

dd. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of Suboxone in Virginia;

ee. W.Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Suboxone in West Virginia;

ff. Wis. Stat. § 100.18; Wis. Stat. § 100.20, *et seq.*, with respect to purchases of Suboxone in Wisconsin;

gg. Wyo. Stat. Ann. § 40-12-101, *et seq.*, with respect to purchases of Suboxone in Wyoming.

COUNT VII:

Insurance Fraud Under State Law
(AGAINST ALL DEFENDANTS)

231. Humana hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

232. Indivior and MonoSol knowingly presented or caused to be presented to Humana statements in support of claims for insurance benefits for Suboxone that it knew contained false and/or misleading information. Indivior knew and intended that by engaging in its Suboxone Scheme that misleading and/or false information would be submitted to Humana and other third-party payors in connection with insurance claims.

233. Indivior and MonoSol have committed insurance fraud in violation of the laws of Kentucky, North Carolina, New Jersey, Pennsylvania and Tennessee, and in particular the following laws:

a. Ky. Rev. Stat. §§ 304.47-020, et seq. (Kentucky);

b. N.C. Gen. Stat. §§ 58-2-160, et seq. (North Carolina);

c. N.J. Stat. §§ 17:33A, et seq. (New Jersey);

d. 18 Pa. Cons. Stat. Ann. §§4117 (Pennsylvania);

e. Tenn. Code Ann. §§ 56-53-103, et seq. (Tennessee).

COUNT VIII:

Unjust Enrichment Under State Law
(AGAINST ALL DEFENDANTS)

234. Humana hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

235. Indivior and MonoSol have benefited from artificial prices in the sale of Suboxone resulting from the unlawful and inequitable acts alleged throughout this Complaint.

236. Indivior's and MonoSol's financial benefit resulting from their unlawful and inequitable acts are traceable to overpayments for Suboxone made by Humana.

237. Humana has conferred upon Indivior and MonoSol an economic benefit, profits from unlawful overcharges, to the economic detriment of Humana.

238. It would be futile for Humana to seek a remedy from any party with whom it has privity of contract for its indirect purchases of Suboxone.

239. It would be futile for Humana to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it purchased Suboxone, as it is not liable and would not compensate Humana for the impact of Indivior's and MonoSol's unlawful conduct.

240. The economic benefit of overcharges derived by Indivior and MonoSol through charging supra-competitive and artificially inflated prices for Suboxone is a direct and proximate result of Indivior's and MonoSol's unlawful conduct.

241. The economic benefits derived by Indivior and MonoSol rightfully belong to Humana, as it paid anticompetitive and monopolistic prices during the relevant period, benefiting Indivior and MonoSol.

242. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Indivior and MonoSol to be permitted to retain any of the overcharges for Suboxone derived from Indivior's and MonoSol's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

243. Indivior and MonoSol are aware of and appreciate the benefits bestowed upon them by Humana.

244. Indivior and MonoSol should be compelled to disgorge in a common fund for the benefit of Humana all unlawful or inequitable proceeds it received.

245. A constructive trust should be imposed upon all unlawful or inequitable sums received by Indivior and MonoSol that are traceable to Humana.

DEMAND FOR JUDGMENT

WHEREFORE, Humana demands judgment against Defendants, as follows:

246. Awarding Humana actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post-judgment interest at the statutory rates;

247. Awarding Humana equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Indivior's unjust enrichment;

248. Declaring the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of fraud and unjust enrichment of the states and territories set forth above;

249. Awarding Humana its reasonable costs and expenses, including attorneys' fees; and

250. Awarding all other legal or equitable relief as the Court deems just and proper.

JURY DEMAND

Humana demands a jury trial on all claims so triable under Federal Rule of Civil Procedure 38(b).

Dated: September 18, 2020

Respectfully submitted,

s/ Jerome P. DeSanto

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**Pro Hac Vice* Application forthcoming

EXHIBIT 1

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Case No.** 1:19CR00016
	)	
INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC	)	**Violations:** **18 U.S.C. §§ 2, 1341, 1343, 1347, 1349**

INDICTMENT

OVERVIEW

The Grand Jury charges that:

1. Suboxone Film is an opioid drug used in the treatment of opioid addiction/dependence. Indivior sells Suboxone Film throughout the United States. Beginning in or about 2010, Indivior executed an illicit nationwide scheme to increase prescriptions of Suboxone Film. In particular, Indivior illegally obtained billions of dollars in revenue from Suboxone Film prescriptions by deceiving health care providers and health care benefit programs into believing that Suboxone Film is safer and less susceptible to diversion and abuse than other, similar drugs. Indivior further sought to boost its profits from Suboxone Film by establishing a telephone program for patients to call to be connected with a doctor for opioid addiction/dependence treatment, which Indivior used to connect patients to doctors Indivior knew were prescribing Suboxone and/or other opioids in a careless and clinically unwarranted manner. Indivior's fraudulent scheme lasted for years and hindered patients', health care providers', and health care benefit programs' accurate assessments regarding opioid-addiction treatment in order to increase the company's profits.

INTRODUCTION

The Grand Jury charges that at times material to this Indictment:

DEFENDANTS

2. INDIVIOR INC. (hereinafter "INDIVIOR") was a Delaware corporation headquartered in Richmond, Virginia, that marketed and distributed prescription drugs containing buprenorphine, an opioid controlled substance, under brand names including Suboxone and Subutex. Until on or about December 23, 2014, INDIVIOR was a wholly owned subsidiary of Company A, and was known as Reckitt Benckiser Pharmaceuticals Inc.

3. INDIVIOR PLC was an English public limited company headquartered in Slough, England, United Kingdom, that owned, controlled, managed, and operated INDIVIOR after on or about December 23, 2014.

HEALTH CARE BENEFIT PROGRAMS

4. Medicare was a health care benefit program under Title 18, United States Code, Section 24(b) that provided basic medical coverage to individuals age 65 or older and to certain disabled persons. The United States Department of Health and Human Services, through the Centers for Medicare and Medicaid Services ("CMS"), administered Medicare through contractors. Medicare Part D paid for certain prescription drugs for Medicare beneficiaries.

5. Medicaid was a health care benefit program under Title 18, United States Code, Section 24(b) that was administered by agencies of the various states to provide health care benefits and services to those who qualified. Medicaid was funded jointly by the states and by CMS and paid for certain prescription drugs for Medicaid beneficiaries.

6. Other public health care programs and private health care insurance providers were health care benefit programs under Title 18, United States Code, Section 24(b) that paid for certain prescription drugs for their beneficiaries.

LEGAL AUTHORITY

7. The Federal Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 301, *et seq.*, provided that no drug could be marketed in interstate commerce unless it had been approved by the Food and Drug Administration ("FDA").

8. The Orphan Drug Act ("ODA"), Title 21, United States Code, Sections 360aa, *et seq.*, provided that the FDA could designate a drug as an "orphan drug," and upon approving the drug, would not approve another drug for the same disease or condition for seven years.

9. The Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), Title 21, United States Code, Section 355(j), provided that the FDA could approve generic drugs without requiring all of the clinical testing required for new drugs.

10. The Drug Addiction Treatment Act ("DATA"), Title 21, United States Code, Section 823(g), authorized registered health care providers to prescribe certain opioid drugs in Schedules III, IV, or V of the Controlled Substances Act ("CSA"), Title 21, United States Code, Section 801, *et. seq.*, for the treatment of opioid addiction/dependence outside a treatment clinic. The DATA limited the maximum number of patients a provider could so treat at any one time. Through in or about July 2016, the maximum limit for any one provider was 100 patients at a time. In or about August 2016, the maximum limit was raised to 275 patients at a time.

11. Title 21, Code of Federal Regulations, Part 1306.04, stated that a prescription for a controlled substance was effective only if issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.

SUBOXONE TABLET AND SUBUTEX TABLET

12. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continued taking opioids under medical supervision, to avoid or reduce withdrawal symptoms while they sought to recover. The only opioid approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take home) was buprenorphine, a Schedule III controlled substance under the CSA.[1]

13. On or about October 8, 2002, INDIVIOR received FDA approval of the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet ("Suboxone Tablet") and Subutex Sublingual Tablet ("Subutex Tablet"). The FDA designated both as orphan drugs, meaning the FDA committed not to approve any competitor drug for seven years (the "exclusivity period").

14. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Daily doses of Suboxone Tablet containing more than 24 milligrams ("mgs") of buprenorphine were not shown to provide any clinical advantage over lower doses. Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps. Before in or about 2013, another subsidiary of Company A manufactured Suboxone Tablet in Hull, England, United Kingdom, and INDIVIOR marketed and distributed it throughout the United States.

[1] Buprenorphine is an opioid partial agonist with a morphine milligram equivalent conversion factor ("MME-CF") 20 times higher than oxycodone.

15. Subutex Tablet was similar to Suboxone Tablet, but did not include naloxone. It was intended for certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps. Before in or about 2011, another subsidiary of Company A manufactured Subutex Tablet in Hull, England, United Kingdom, and INDIVIOR distributed it throughout the United States.

SUBOXONE FILM AND THE PLAN TO MARKET IT

16. By in or about 2007, INDIVIOR's and Company A's annual revenue from sales of Suboxone Tablet and Subutex Tablet had grown to more than $260 million, but they forecast they would lose most of that revenue to competitor drugs, particularly generic versions of Suboxone Tablet, after the exclusivity period ended on October 8, 2009.

17. Between in or about December 2006 and March 2007, INDIVIOR and Company A began developing a new buprenorphine-containing drug for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Film ("Suboxone Film"). They believed Suboxone Film would be protected by patents. They planned to promote Suboxone Film by claiming it was safer than alternative drugs such as tablets, though there were no scientific studies to establish that claim.

18. Additionally, between in or about December 2006 and March 2007, INDIVIOR, Company A, and others discussed ways to delay FDA approval of generic versions of Suboxone Tablet by discontinuing Suboxone Tablet under the pretext of a safety concern, thereby triggering FDA safety-related processes that could take as long as a year. They wrote, "We could tie up generic for 1 year . . . . When we file for film and withdraw tablet [the FDA] is precluded from approving another tablet until they have made a determination in response to a petition from generic company to determine that product was not withdrawn for safety or

efficacy;" a "negative safety issue" could "prevent approval of generic;" "We need to think creatively about a safety story;" "we probably also need to think very negatively about [tablets] and identify aspects that could be unsafe;" "We cannot prevent generics . . . We can delay;" and a timeline for how long generics could be delayed.

19. On or about October 20, 2008, INDIVIOR submitted a new drug application ("NDA") for Suboxone Film to the FDA. (INDIVIOR did not seek approval of a film version of Subutex.)

20. Like Suboxone Tablet, Suboxone Film contained buprenorphine and naloxone, was intended to be taken by placement under the tongue until dissolved, and daily doses containing more than 24 mgs of buprenorphine were not shown to provide any clinical advantage over lower doses. However, Suboxone Film differed from Suboxone Tablet in that it had a thin form; stuck to the tongue/mouth; dissolved more rapidly; potentially had higher bioavailability at certain doses; was formulated to taste better; and typically was dispensed by pharmacies in individually wrapped, child-resistant foil pouches each bearing a serial number.

21. Between in or about May 2009 and August 2010, while awaiting FDA approval of Suboxone Film, INDIVIOR managers drafted marketing plans for the drug. The draft plans listed "Key Success Drivers" for Suboxone Film such as "Driving physician prescriptions for Suboxone film," "Driving formulary support for Suboxone film through payors," and "Driving patient Suboxone film trial," and included the messages that Suboxone Film was "a more responsible medication from a public health perspective," was a "less divertible/abusable formulation," and had a "lower risk of child exposure," and that generic drugs would "jeopardize the entire disease space," though there were no scientific studies to establish these claims. The draft plans noted that public health care benefit programs such as Medicare, Medicaid, and the

Veterans Administration paid for 27% of all Suboxone Tablet and Subutex Tablet prescribed, while private health care benefit programs paid for 55%.

22. On or about June 9, 2009, INDIVIOR's medical director told fellow INDIVIOR medical personnel, "We need to develop a story about childhood exposures to set the stage for switching patients to" Suboxone Film.

23. On or about August 21, 2009, the FDA declined to approve INDIVIOR's NDA for Suboxone Film because it did not contain an adequate risk evaluation and mitigation strategy ("REMS") to address the FDA's concerns about misuse, abuse, and accidental overdose.

24. On or about October 5, 2009, INDIVIOR sent a letter to the FDA, asking whether the FDA agreed that Suboxone Film's packaging would protect against diversion (*e.g.*, illegal selling, sharing, and smuggling of Suboxone) and accidental child exposure (*i.e.*, children taking Suboxone by accident). The FDA did not immediately respond. INDIVIOR executives and others internally discussed that the FDA could disagree, for reasons including that it was not clear how physicians would use the serial numbers on Suboxone Film packages to deter diversion, and "there is an incremental risk of the film since once a child ingests the film it will be nearly impossible to remove vs. tablets."

25. On or about November 24, 2009, INDIVIOR resubmitted its NDA for Suboxone Film to the FDA, including a REMS.

26. On or about January 22, 2010, INDIVIOR's chief executive officer told Company A executives, "Our immediate focus is to get the FDA approval for [Suboxone Film] asap to switch the business ahead of the generic."

27. On or about March 29, 2010, the FDA responded to INDIVIOR's October 5, 2009 letter that sought the FDA's agreement that Suboxone Film's packaging would protect against diversion and accidental child exposure, stating:

> The Agency will not comment on whether the serial numbers [on Suboxone Film's packaging] would lead to a decrease in diversion of a drug product, because drug diversion issues are regulated by DEA.
>
> * * *
>
> No, we do not agree that the packaging for [Suboxone Film] provides meaningful incremental protection against pediatric exposure. Although the foil pouches fulfill the child resistant effectiveness standards and the foil pouch bears warning statements alerting patients to keep out of reach of children, no data were provided to support that these measures will encourage patients to store [Suboxone Film] in a manner which prevents accidental pediatric ingestion. Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial doses that are neither in the child-resistant pouch nor in a child-resistant medication bottle. Furthermore, because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.

28. INDIVIOR executives, managers, and personnel understood from the FDA's response that they lacked substantiation to inform health care providers that Suboxone Film was safer than alternative drugs such as tablets. INDIVIOR executives and managers wrote to each other, "The FDA has stated that we have no proof that patients will not take the film out of the [pouch] and cut it into multiple doses. Thus not reducing potential exposure . . . . Even then the FDA points out that the film may not be swallowed thus making more buprenorphine available;" that the FDA's response could "be a bigger issue as it may imply the overall risk/benefit is not favorable for our film (vs tablet);" and, "It looks like they are trying to deny us the ability to make a claim on additional paediatric safety of the film." With regard to misuse, abuse, and

diversion, INDIVIOR executives, managers, and personnel knew that Suboxone Film's thin form potentially could make it easier to conceal, and thus more susceptible to smuggling than tablets; its individual packaging could make it more portable, including for reselling and sharing; and the serial numbers on the pouches were not electronically tracked and not shown to deter diversion. With regard to accidental child exposure, they knew that Suboxone Film had attributes that potentially could make it more dangerous to children, including that it stuck and could not easily be spit out if accidentally taken by a child; dissolved more rapidly, leaving less time to remove it from a child's mouth before absorption; had potentially higher bioavailability at certain doses, potentially increasing the severity of an incident; was formulated to taste better, potentially reducing the likelihood that a child would seek to remove it; and could not easily be re-secured in its original packaging, which, unlike a bottle with a child-resistant cap, was not designed to be re-closed.

29. On or about August 30, 2010, the FDA approved Suboxone Film, including the REMS and prescribing information for the drug. None of these materials stated that Suboxone Film was safer than alternative drugs such as tablets, or reduced the risk of misuse, abuse, diversion, or accidental child exposure. Nevertheless, INDIVIOR's chief executive officer told Company A executives including its chief executive officer and chief financial officer, "We will be making the most of every minute between now and generic approval to convert our tablet business to film," including a "Full Blitz campaign for salesforce through Thanksgiving." For the full blitz campaign, INDIVIOR salespeople planned to raise "diversion and misuse and pediatric safety" in sales presentations to physicians, even though there were no scientific studies to establish that Suboxone Film was safer with regard to diversion, misuse, or pediatric safety.

30. Suboxone Film was manufactured by another subsidiary of Company A in Hull, England, United Kingdom, and a third party in Portage, Indiana. INDIVIOR marketed and distributed it throughout the United States.

THE SCHEME AND ARTIFICE TO DEFRAUD

31. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents did devise and intend to devise a scheme and artifice to defraud and to obtain money and property from health care benefit programs by means of materially false and fraudulent pretenses, representations, and promises, by (A) making materially false and fraudulent statements and representations to health care providers to induce them to prescribe, dispense, and recommend Suboxone Film; (B) preparing and causing to be prepared, and shipping and causing to be shipped, materially false and fraudulent marketing materials promoting Suboxone Film; (C) making materially false and fraudulent statements and representations to and relating to state Medicaid administrators and others to promote Suboxone Film; and (D) marketing Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner.

A. MATERIALLY FALSE AND FRAUDULENT STATEMENTS AND REPRESENTATIONS TO HEALTH CARE PROVIDERS

32. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, materially false and fraudulent statements and representations to health care providers to induce them to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film.

33. On or about September 2, 2010 (about three days after Suboxone Film received FDA approval), Company A's chief executive officer emailed approximately 20 INDIVIOR executives and managers, including INDIVIOR's chief executive officer and marketing personnel, stating that Suboxone Film was "safer," and encouraging them to "convert [patients] from tablets to films, thereby protecting our Net Revenues in the USA."

34. On or about September 6, 2010 (about a week after Suboxone Film received FDA approval), an INDIVIOR national sales supervisor emailed approximately 50 INDIVIOR salespeople, encouraging them to tell physicians that Suboxone Film was "safer because of the packaging."

35. On or about October 17, 2010, INDIVIOR's chief executive officer told INDIVIOR personnel to revise the performance appraisals and incentive programs for salespeople to reward "film sales only." He stated that INDIVIOR's salespeople had "every possible resource to enable them to generate demand for a scheduled narcotic that is being given away for free to an addicted population," and those without "adequate film sales" may be fired. Thereafter, INDIVIOR revised the performance appraisals and incentive programs to be based primarily on the percentage of Suboxone Film compared to tablet sales in the salesperson's territory (sometimes called the "film market share" or "film share").

36. On or about October 25, 2010, INDIVIOR sales supervisors discussed baseless "dialogue points" that INDIVIOR salespeople were using to highlight Suboxone Film's "advantages" to physicians and pharmacists, which included "Reduced misuse/diversion" and "Public safety – reduced pediatric exposure." On or about November 3, 2010, an INDIVIOR sales supervisor emailed the dialogue points to INDIVIOR's chief executive officer.

37. In or about December 2010, INDIVIOR's vice president for clinical affairs met with physicians in California and elsewhere, and in the presence of INDIVIOR salespeople, materially falsely and fraudulently stated to the physicians that Suboxone "Film addresses child safety and abuse and diversion" and was a "safer product."

38. On or about February 14, 2011, an INDIVIOR national sales supervisor instructed a regional sales supervisor in Michigan and a sales representative in Ohio to:

> not be afraid to let the physician know very clearly what you believe. If you believe that Suboxone Sublingual Film will lower pediatric exposure, or lower diversion and misuse let them know. You are the expert and because of all you have done, the relationships you have built, they will be receptive to what you believe.

39. On or about March 11, 2011, Company A's chief executive officer materially falsely and fraudulently stated in Company A's public 2010 annual report that Suboxone Film was "better from a child safety point of view, mak[ing] it more attractive for doctors to prescribe."

40. On or about April 13, 2011, INDIVIOR's chief executive officer materially falsely and fraudulently stated in a corporate newsletter that Suboxone Film "has the potential for greater child safety."

41. In or about July 2012, at a Company A investor presentation, in the presence of Company A's chief executive officer, INDIVIOR's chief executive officer materially falsely and fraudulently stated that Suboxone Film was "less divertable and abusable."

42. On or about the specified dates, in or around the specified states, INDIVIOR sales representatives reported to their supervisors and their fellow sales representatives to use as models for promoting Suboxone Film, the below-described statements and representations made to physicians, pharmacists, and other health care providers to materially falsely and fraudulently

induce them to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film:[2]

Par.	Date	State	Report
43	9/1/2010	NY	INDIVIOR sales representative told physicians that Suboxone Film "offers increased protection against misuse/abuse/diversion and pediatric exposure. Due to this, and the fact that patients will be able to get the film at no cost, they have all stated that they will prescribe the Film when it is available. . . . Most pharmacists have also been impressed with the new formulation and the steps the company has taken to decrease diversion and pediatric exposure"
44	9/10/2010	NC	INDIVIOR sales representative told a physician that Suboxone Film "offers greater protection against pediatric exposure & misuse/diversion"
45	9/30/2010	SC	INDIVIOR sales representative met with a physician and "[d]iscussed pediatric exposure & tablet diversion as reasons for MD to insist that pts switch from tablet to film"
46	12/16/2010	MI	INDIVIOR sales representatives told physicians that Suboxone Film is the "safest choice," has "less chance of inadvertent use by kids," can "protect the community;" and can "protect office-based treatment" from being banned
47	12/21/2010	CA	INDIVIOR sales representative told physicians that Suboxone Film "is a better safer medication" and "it would be unethical or inappropriate for us to promote the tablet now that we have a better, safer product"
48	12/22/2010	MI	INDIVIOR-paid speaker told physicians that her "big plus for the Film was the packaging and therefore making it a safer product for the community"
49	12/22/2010	TN	INDIVIOR sales representative told physicians that during the holiday season, Suboxone Film gives patients "added comfort in knowing their medication is safer to have in the home as family and friends with small children will be visiting more"
50	1/6/2011	MI	INDIVIOR sales representative met with a physician who was "in the category of trying out the film but not yet sold on it," and stated that "it's important [for the physician] as a physician and mom to convert patients to the Film. The fact that film helps to protect [office-based opioid treatment] and reduces pediatric exposure appeared hard to ignore for the doctor. Hopefully that message will have a louder voice in her head than the patients telling her they are 'happy' with the Tablet"
51	1/11/2011	CA	INDIVIOR sales representative told physician and pharmacists that Suboxone Film is a "safer product vs tablet"
52	2/3/2011	IN	INDIVIOR sales representative told a physician that patients who request tablets do so "in order to divert them. [The physician] said that he may have become a bit too trusting in his several years of treat[ing] patients. We spoke about how the Film can 'weed out' those patients truly not committed to recovery. He promised to convert ALL patients to Film"
53	2/3/2011	UT	Physicians told an INDIVIOR sales representative that patients were "complaining about the Film and asking to be put back on the tablet." INDIVIOR sales

[2] These are illustrative examples, not an exhaustive list.

			representative responded by discussing "misuse and abuse of Suboxone tablets and how the Film is the better, safer choice. I know that we will have more followup in this office, due to these doctors' new awareness of what is really happening when some ask to be switched back to the tablet"
54	2/9/2011	TX	INDIVIOR sales representative told physicians "that many other doctors are going 'film only' because they want to provide the best quality care to their patients with the most efficacious, safest, and cost saving treatment and it has influenced several of them and they then have been interested in how others are doing this, how patients are responding, etc. I believe it makes them feel more confident to know that others are doing this and it also makes them want to do the same to keep up with 'quality care' physicians"
55	3/2/2011	TX	INDIVIOR sales representative told physicians that Suboxone Film is "newer, easier, quicker and most importantly safer for the patients and their families, the physicians and community"
56	3/2/2011	IN	INDIVIOR sales representative met with a pharmacist and "had a candid discussion as to why some patients want so badly to stay on the tablet even at a higher price to them (diversion). [The pharmacist] is going to 'hammer away' at [doctors who prescribed tablets] to get these patients on Film"
57	4/13/2011	IL	INDIVIOR sales representative told a physician and a pharmacist about "some of the blogs I have read and about the reported child death. This seemed to really impact them, and [the physician] said he has had some concern about a few patients in the past. We discussed that while the film cannot stop misuse and diversion, it can help prevent it, and our hope is to decrease the misuse and diversion, as well as the number of pediatric exposures. The pharmacist in the building also attended the [presentation] and everyone agreed that if a patient came to the pharmacy with a prescription for the tablet, the pharmacist would call back the office to see if it could be switched to film"
58	4/14/2011	CA	INDIVIOR sales representative told a physician that Suboxone Film is "safer, better, and cheaper than the pills. What reason do you have not to convert all of your patients to the film? She could not give a reason. She said she will switch her patients"
59	5/10/2011	CA	INDIVIOR sales representative told a physician that she would not help the physician enroll in a patient-referral program "unless I knew those patients seeking treatment would get a Comprehensive approach that includes the Safest Medication on the Market for Opioid Dependency which is the Film"
60	5/26/2011	UT	INDIVIOR sales representative told physicians that Suboxone Film is "safer to have around their family members"
61	6/8/2011	VA	INDIVIOR sales representative told physicians that one doctor in the area "converted all patients to Film and no longer give[s] a choice [between tablets and film] due to rampant diversion of the tablet in the area, which borders Virginia, Kentucky and Tennessee. This has been a great win and is something that I've been able to tell all my other docs who have converted most of their patients but not all"
62	7/7/2011	NC	INDIVIOR sales representative met with a physician who was "still giving [some] patients the choice between the Suboxone Film and tablet . . . . I strongly encouraged [the physician] to protect herself, her practice and her medical license

			by prescribing Suboxone film to ALL of her patients. I said, 'I don't want any of my physicians to find themselves on a witness stand defending their decision for prescribing Suboxone tablets which caused the death of a child.' Hopefully that statement convinced [the physician] to adopt a fail first policy on the Suboxone film"
63	7/7/2011	OR	INDIVIOR sales representative asked a physician what was "holding [him] back from the patient-preferred Film?" The physician stated that his "tablet patients are doing well and are afraid of changing when they are doing well." The INDIVIOR sales representative then "talked about Tablet exposures to children and how [the physician] can be their safety net by prescribing the Film rather than the Tablets which he agreed with"
64	7/7/2011	CA	INDIVIOR sales representative was "working diligently with [a physician] in order to get him to transition his considerable amount of tablet patients to the Film. I am making progress with him. He's been reluctant and has allowed his patients the choice [between tablets and film]. I believe I've instilled in him the importance of protecting public safety and [office-based opioid treatment], and how, by prescribing the Film, he will help to make that happen"
65	7/18/2011	PA	INDIVIOR sales representative "had an excellent conversation with [physicians] around more of the reasons why [they] might want to move more of their patients off of tablets and onto the Film. They agreed it was a safer option and are proud they are doing their part to protect our community"
66	7/21/2011	DE	INDIVIOR sales representative met with physicians and pharmacists, "capitalizing on the Public Health Message and the importance of providing patients with a safer option in the film"
67	7/21/2011	PA	INDIVIOR sales representative told physicians, "You get the same clinical efficacy [with Suboxone Film] as you get with tablets, possibly greater compliance with improved taste and dissolve time, safety is improved within the public and the home, and most patients get the Film for virtually free with the Savings program. Why take the chance?"
68	9/2/2011	MD	INDIVIOR-paid speaker told physicians that Suboxone Film was "preventing pediatric death in graphic terms"
69	10/26/2011	TN	INDIVIOR sales representative "led physicians to the internet so that they may see how their decisions to prescribe any tablet over [Suboxone Film] may have a negative impact on the community. There are current articles that [the tablet] kills children all over the internet and this helps them to see the reasons to prescribe [Suboxone Film] over the tablets. . . . One of my doctors . . . still has not converted all of his patients to [Suboxone Film]. He was able to visit the internet article to see how [Suboxone Film] could put safe guards in the community as well as in his practice. Once he saw this information he committed to write all of the [tablet] patients [Suboxone Film]. From the look on his face [he] was really concerned about the safety of his patients"
70	11/11/2011	VA	INDIVIOR sales representative made the following presentations to physicians: "The physicians agree that we all have an obligation to protect the public health. I have each physician [say] if they agree that it starts with THEM, the prescriber? They do agree. Then WHY would you not prescribe the SAFEST medication available? Is it worth the risk of pediatric exposure? Is it worth the risk of abuse

			and diversion? Is it worth the risk of ending office based treatment? It starts with YOU, DOCTOR! Unfortunately, it does NOT end with you! It can end with unintended consequences in the hands of people suffering from a terrible disease, who are not known for making the best decisions! These discussions have really opened the eyes of quite a few physicians who now realize their obligation." INDIVIOR sales supervisor singled out this presentation as a model presentation, forwarding it to other INDIVIOR salespeople
71	12/5/2011	IL, IN, KY, MI, OH, TN, WV	INDIVIOR sales representative collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone Film from others across the region, including "Baby Death articles;" "Diversion with Tablets and high street value of $25.00 per pill;" "Film harder to sell on streets;" "if patients call office and ask if doctor writes the tablets (or pills) that is a patient you do not want—they will be diverting and your office can or will be tied to that illicit drug;" "I inform my doctors (and pharmacists) that insurance companies are beginning to view the film the same way we do . . . as the superior (safer) product;" "I focus on the safety for their office as well as the general public, the fact [Suboxone Film] will weed out the drug seekers and it will make their offices respectable and full of patients who are serious about their recovery;" and "Patients are tempted to share especially when they are doing well and want to help people that they care about . . . . [Suboxone Film] will reduce this possibility"
72	2011	AZ, CA, CO, LA, MO, OR, TX, UT	INDIVIOR sales representatives collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone Film from others across the region, including "Once the dialogue opens up about community, safety etc, I explain that we believe [Suboxone Film] is the safest medication available;" "[by] providing the safest medication (FILM) you (physician, pharmacist, counselor, office staff) are helping the patient 'close the gaps' in their treatment as well as reducing the chance of misuse, abuse and diversion, which increases public safety;" "Do you agree the Film is safer and less abusable than the tablet?;" "[Suboxone Film is] a safer alternative to the tablet – safer for the patients, safer for their families and more aligned with [INDIVIOR's] goal to protect office-based treatment;" and asking physicians "to imagine how devastated [their] patients would be if one of those children were to get into a bottle full of Suboxone tablets"

73. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents knew that messages like those described in paragraphs 33-72 of the Introduction to this Indictment materially influenced health care providers to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film. In or about January 2011, an INDIVIOR contractor reported to INDIVIOR executives, managers, and personnel that in a survey of 245 physicians who had

prescribed Suboxone Film, 68 physicians (approximately 28%) stated that they did so because it "[d]ecreases misuse/abuse/diversion," and 26 physicians (approximately 11%) stated that they did so for "[s]afety re: inadvertent use by children." Additionally, the physicians rated "Ability to minimize unintentional pediatric exposure" and "Reduces the likelihood of misuse & diversion" as the second and third leading reasons to prefer Suboxone Film, respectively.[3] More than 80% of the physicians, and 98% of the high-prescribing physicians, stated that they learned about Suboxone Film from INDIVIOR salespeople.

74. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents knew that the messages described in paragraphs 33-72 of the Introduction to this Indictment, and others like them, were false and fraudulent. In addition to the FDA's letter of March 29, 2010, informing INDIVIOR that it lacked substantiation to claim that Suboxone Film better protects against accidental child exposure (discussed above), on or about June 30, 2011, an INDIVIOR contractor reviewing information as part of the Suboxone Film REMS told INDIVIOR that Suboxone Film was more frequently abused parenterally (*e.g.*, by injection) and involved in more accidental child exposures per million doses than Suboxone Tablet. INDIVIOR did not alert patients, physicians, pharmacists, health care benefit programs, or others to these findings, which cast doubt on INDIVIOR's promotional messages about Suboxone Film. Subsequently, between in or about December 2011 and February 2012, INDIVIOR's compliance committee determined that INDIVIOR salespeople's written reports of their promotional statements to physicians and pharmacists (examples of which are set forth in paragraphs 43-72, above) posed "compliance risks," and discontinued the reports, without contacting patients, physicians, pharmacists, health

[3] "Speed of dissolving" was first.

care benefit programs, or others to correct or retract the promotional statements reflected in the reports. In or about November 2012, INDIVIOR's medical director, vice president for clinical affairs, and others discussed attributes of Suboxone Film that potentially could make it more dangerous to children, such as that, "With a tablet, they've got options. They can spit it out. They can swallow it. With the film, not necessarily. We know, it's stuck" in the child's mouth.

75. In or about 2012-13, INDIVIOR managers discussed that, "Under no circumstances can we make the claim that Suboxone Film is safer or better at reducing pediatric exposures," and "Saying Suboxone Film is safer than any tablet on the market because Film has less ability to be snorted/injected [is an] unsubstantiated superiority claim," but did not contact patients, physicians, pharmacists, health care benefit programs, or others to correct or retract the promotional statements INDIVIOR salespeople had already made.

B. MATERIALLY FALSE AND FRAUDULENT MARKETING MATERIALS PROMOTING SUBOXONE FILM

76. Between in or about 2010 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents prepared and caused to be prepared, and shipped and caused to be shipped by mail and private or commercial interstate carrier to their executives and employees and others throughout the United States, written marketing materials used to promote Suboxone Film that contained materially false and fraudulent statements and representations, including the following:

a. Suboxone Film was "Helping Address Public Health Needs;"

b. Suboxone Film could "Help Address Misuse and Abuse;"

c. Suboxone Film "Can Be Part of the Solution" to "misuse," "diversion and abuse," and "unintentional pediatric exposure;"

d. "Nearly half of Suboxone Film prescribers surveyed cited 'potential for reduction of abuse and diversion' as a reason to prescribe vs Suboxone Tablet," when in fact, only 28% of the prescribers had cited that supposed reason, many of them after receiving fraudulent sales presentations from INDIVIOR;

e. A false and fraudulent chart with the heading, "Suboxone Film—Helping to Reduce the Risk of Pediatric Exposure," that purported to depict pediatric exposure data for Suboxone Tablet and Suboxone Film, but intentionally omitted other data from the same study that showed that buprenorphine-only tablets also had low pediatric exposure, and therefore called into question the claim that Suboxone Film reduced pediatric exposure. An INDIVIOR employee asked INDIVIOR's medical director, "I couldn't help but notice that the chart did not show the [buprenorphine-only tablets] line. Does that mean we can also show the graph without [that] line? That would make such a huge difference!" INDIVIOR's medical director responded, "That chart is now published so nock [sic] yourself out!"

f. A false and fraudulent pair of charts with the heading, "Suboxone . . . Film—associated with lower rates of diversion and abuse . . ." that purported to depict diversion and abuse data for Suboxone Tablet, buprenorphine-only tablets, and Suboxone Film, but intentionally omitted two other charts from the same page of the same study that showed that Suboxone Tablet and buprenorphine-only tablets had diversion and abuse rates similar to Suboxone Film during certain time periods, and therefore called into question the claim that Suboxone Film was associated with lower rates of diversion and abuse.

77. On various dates, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents shipped and caused to be shipped by mail and private or commercial interstate carrier, copies of marketing materials described in paragraph 76 of the Introduction to this Indictment, from a contractor in New Jersey to sales representatives throughout the United States, including:

a. a sales representative in Roanoke, Virginia, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Blacksburg, Cedar Bluff, Charlottesville, Christiansburg, Danville, Galax, Lynchburg, Roanoke, Salem, Staunton, Willis, and Wytheville, Virginia, and

b. a sales representative in Greeneville, Tennessee, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Abingdon, Big Stone Gap, Bristol, Coeburn, Glade Spring, Lebanon, Marion, Norton, Pennington Gap, Pound, Saint Charles, Tazewell, and Wise, Virginia.

C. MATERIALLY FALSE AND FRAUDULENT STATEMENTS AND REPRESENTATIONS TO AND RELATING TO STATE MEDICAID ADMINISTRATORS AND OTHERS

78. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, statements and representations that INDIVIOR was discontinuing the distribution of Suboxone Tablet due to safety concerns, when in fact, the reason for discontinuing the distribution of Suboxone Tablet was to delay the FDA's approval of generic versions of Suboxone Tablet.

79. Between on or about January 6, 2012, and September 14, 2012, INDIVIOR and Company **A**, knowing that potential competitors were preparing applications for FDA approval

of generic versions of Suboxone Tablet, retained contractors to review and analyze notes of telephone calls to poison control centers regarding accidental child exposure.

80. On or about June 21, 2012, Company A's investor relations director emailed Company A's chief executive officer, INDIVIOR's chief executive officer, and others, referencing "our plans" to withdraw Suboxone Tablet's FDA approval in order to delay FDA approval of generic versions of Suboxone Tablet. Company A's general counsel responded by emailing Company A's chief executive officer, chief financial officer, and investor relations director, and INDIVIOR's chief executive officer and general counsel, and others, stating, "please do not create any emails or other documents suggesting that we would consider" attempting to delay FDA approval of generic versions of Suboxone Tablet in this way, and "any decision we make will be based on consumer safety."

81. On or about August 31, 2012, INDIVIOR's and Company A's contractors provided them with an "interim report" that failed to include any finding that Suboxone Film was safer than tablets with regard to accidental child exposure, or caused any drop in exposures. The interim report stated, "there remains considerable uncertainty in our ability to use root cause analysis for identifying the role of select factors in these unintentional pediatric exposures," and that the data were "insufficient to make any final conclusions regarding the severity of effects associated with specific buprenorphine medications or the child-resistance efficacy of product packaging types." The INDIVIOR manager overseeing the project stated that the interim report was a "worthless, empty shell."

82. On or about September 14, 2012, INDIVIOR executives caused the preparation of a public relations strategy for discontinuing Suboxone Tablet, indicating that INDIVIOR would dispel the "[p]erception of discontinuation as a means for blunting generic/competitive entry"

and convey a "'[w]e must be responsible' sentiment." On or about the same day, INDIVIOR's and Company A's contractors provided INDIVIOR and Company A with a three-page "executive summary" that failed to include any finding that Suboxone Film was safer than tablets with regard to accidental child exposure, or caused any drop in exposures. The summary stated that there were fewer references to Suboxone Film than tablets in the telephone call notes, but the reasons for this could not be determined, and "any results related to the original packaging should be interpreted with considerable caution" because many of the notes did not indicate whether the drug had been in the packaging or left outside the packaging by an adult.

83. On or about September 18, 2012 (about four days later), INDIVIOR and Company A sent a "Notice of Discontinuance" of Suboxone Tablet to the FDA, stating that the reason for the discontinuance was "increasing concerns regarding pediatric exposure to" Suboxone Tablet. INDIVIOR's and Company A's respective chief executive officers approved the notice, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

84. On or about September 25, 2012, INDIVIOR and Company A submitted a petition to the FDA, signed by INDIVIOR's medical director, stating that INDIVIOR discontinued Suboxone Tablet "due to safety concerns" about tablets, and asking the FDA not to approve generic versions of Suboxone Tablet. INDIVIOR's and Company A's respective chief executive officers approved the petition, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

85. The petition referenced a new, five-page version of the executive summary, which INDIVIOR and Company A executives and others had participated in altering, but kept dated September 14, concealing the fact that it was altered from the version they originally cited for

discontinuing Suboxone Tablet. The alterations included deleting the statement that "any results related to the original packaging should be interpreted with considerable caution," and adding conclusions.

86. On or about September 25, 2012, Company A posted on its website a press release stating that Suboxone Tablet was discontinued "due to increasing concerns with pediatric exposure." INDIVIOR's and Company A's respective chief executive officers approved the press release, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

87. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents used the discontinuation of Suboxone Tablet to materially falsely and fraudulently market Suboxone Film. Between on or about September 18, 2012, and the date of this Indictment, they prepared and caused to be prepared, and shipped and caused to be shipped by mail and private or commercial interstate carrier to their executives and employees and others throughout the United States, letters signed by INDIVIOR's medical director and used to promote Suboxone Film that contained materially false and fraudulent statements and representations, including the following:

a. "Dear Patient . . . The decision to take Suboxone Tablets off the market was a voluntary choice made by [INDIVIOR] as a result of recent information the company received showing higher rates of accidental pediatric exposure (when a child accidentally takes the medicine) linked with the tablet form. If you are currently taking Suboxone Tablets, continue taking your medication and ask your doctor about how to transition to Suboxone Film. . . ."

b. "Dear Healthcare Professional . . . As we continue to work together to improve the health and well-being of opioid-dependent individuals, we would like to personally inform you about an important medication update . . . . The decision to discontinue Suboxone Tablets was based on accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone [Film] compared with the tablet form. . . . We remain committed to supporting you with updated information and resources to ensure you have the tools you need to educate and transition your patients to Suboxone Film. . . . We thank you for your continued support of [INDIVIOR] as we uphold our commitment to patients and the safety of the public."

88. On various dates, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents shipped and caused to be shipped by mail and private or commercial interstate carrier, copies of marketing materials described in paragraph 87 of the Introduction to this Indictment from a contractor in New Jersey to sales representatives throughout the United States.

89. On or about December 4, 2012, the lead researcher from one of INDIVIOR's and Company A's contractors that had reviewed and analyzed notes of telephone calls to poison control centers emailed fellow researchers, stating that by using the research to supposedly justify discontinuing Suboxone Tablet, INDIVIOR and Company A "played us as a pawn and continues to do so. They are smart people, and they are playing a Machiavellian game."

90. It was also a part of the scheme and artifice to defraud that INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, materially false and fraudulent statements and representations to and relating to state Medicaid administrators and others, claiming that

Suboxone Film was safer than tablets with regard to misuse, abuse, diversion, and accidental child exposure. These materially false and fraudulent statements and representations included representations by employees, physicians, and agents, acting on behalf of the defendants, including those on or about the dates set forth below, in or around the specified states, and sent by the physician, employee, or agent identified below:[4]

Par.	Date	State	Sent by	False and Fraudulent Statement and Representation
91	5/17/2011	MA	Physician, at direction of INDIVIOR Gov. Mgrs.	Op-Ed Letter to The Boston Globe, The Boston Herald, and The Patriot Ledger: Suboxone Film was "preventing diversion, recidivism, and the accidental death of inquisitive children," and by declining to provide Medicaid coverage of Suboxone Film, MassHealth officials were "engaging in 21st century biological warfare, no different than giving small pox infected blankets to the Indians"
92	5/30/2011	CA	INDIVIOR Publicist	Quote for article in Alcoholism & Drug Abuse Weekly, News for Policy and Program Decision-makers: "the main value of [Suboxone Film] is that it is less easily diverted because physicians can track the numbered unit-dose packaging, and it is safer because the packaging is child-resistant." INDIVIOR's marketing director emailed INDIVIOR's chief executive officer, president, medical director, and others stating that "[t]here does seem to be some liberty taken with regards to early comments attributed to" INDIVIOR's publicist, but INDIVIOR did not correct or retract the comments
93	6/23/2011	MA	Physician, at direction of INDIVIOR Gov. Mgrs.	Email to MassHealth officials: "there is less opportunity for diversion with" Suboxone Film, "there is less chance that a curious child will ingest the film," and "the inaction by the policy makers of MassHealth can be seen just as Strom Thurmond's filibuster in opposition of the Civil Rights Act of 1957." Physician subsequently emailed INDIVIOR Gov. Mgrs. requesting that INDIVIOR donate $30,000 to his foundation and give him a Harley-Davidson Road King motorcycle as payment
94	10/16/2012	MA	INDIVIOR Med. Mgr.	Email to MassHealth pharmacy director: altered, inaccurate pediatric exposure data for Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets, making it appear as though Suboxone Film had the lowest rate of pediatric exposure in Massachusetts when, in fact, buprenorphine-only tablets did. INDIVIOR Med. Mgr. sent INDIVIOR's medical director email chains showing that she had altered the data, and stating that

[4] These are illustrative examples, not an exhaustive list.

				she sent the altered data to "help us get some movement in Mass" on Medicaid coverage of Suboxone Film. Upon receiving additional data unfavorable to Suboxone Film, INDIVIOR Med. Mgr. declined to provide it to Medicaid personnel, and told INDIVIOR government managers that her rationale for withholding the unfavorable information from Medicaid personnel was, "don't ask, don't tell"
95	4/18/2013	KY	INDIVIOR Gov. Mgr. and INDIVIOR Med.	Email to KY Department for Medicaid Services commissioner and other officials: Compared to Suboxone Film, the tablet form "increases the risk of diversion with adult recipients because it can be crushed and snorted. . . . [S]ometimes leadership requires you to make a decision locally to protect the residents of the State of Kentucky that you serve. You've chosen not to . . . ."
96	Before 12/2013	KY	INDIVIOR Sales Representative	Model form letters shown to physicians to send to KY Department for Medicaid Services contractors: request for pre-authorization for payment of Medicaid claims for Suboxone Film because "Suboxone filmstrips are medically necessary to properly manage the post acute withdrawal process. Filmstrips are necessary in lieu of sublingual tablets because many adverse side effects are found to be prevalent in tablet form. Patient's [sic] present with constant salivation, discomfort, agitation, dissolution unnecessary prolonged. Also, feelings of disorientation, plus a craving for tablets in general, thus hindering the addiction recovery process and increasing probability of relapse. Use of filmstrips has diminished the adverse side effects of tablets. Use of filmstrips eliminates the abuse of tablets, and variation from the prescribed method of ingestion"

D. MARKETING SUBOXONE FILM TO HEALTH CARE PROVIDERS TO BE PRESCRIBED AND DISPENSED IN A CARELESS AND CLINICALLY UNWARRANTED MANNER

97. Beginning on an unknown date, but no later than on or about April 9, 2009, and continuing through the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents did aid, abet, counsel, command, induce, and procure physicians at various locations throughout the United States who they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of

buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner, to switch their prescribing to Suboxone Film.

98. One way in which INDIVIOR encouraged physicians to prescribe Suboxone Film was by including them in INDIVIOR's internet and telephone referral program, called "Here to Help." Patients and prospective patients could use the "Locate a Doctor" tool on the Here to Help website to find physicians prescribing buprenorphine-containing drugs, and could call the Here to Help hotline to receive information about certain physicians and have the call transferred to a physician's office to schedule an appointment. INDIVIOR salespeople told physicians that Here to Help was "like a concierge service."

99. Additionally, INDIVIOR salespeople provided physicians with marketing materials, billing advice, and access to lunch and dinner events through INDIVIOR's "Treatment Advocate" speaker program, including physicians they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner.

100. INDIVIOR executives, employees, and personnel knew from statistical and firsthand reports that certain physicians had prescribed buprenorphine-containing drugs to substantially more patients at a time than allowed by the DATA, at daily doses higher than 24 mgs of buprenorphine, and in a careless and clinically unwarranted manner. No later than in or about April 2009, INDIVIOR managers began receiving statistical reports that identified physicians overprescribing buprenorphine-containing drugs. One manager emailed another, copying INDIVIOR's medical director, stating, "It takes only a short time perusing the

[statistical reports] to realize that we have some serious breaches of [the DATA law's cap on the number of patients a physician may treat] along with very careless and clinically unwarranted prescribing behaviors (% of patients above 24mg)," and certain physicians "need to be removed from the [buprenorphine] practice arena." INDIVIOR managers also received firsthand reports from INDIVIOR salespeople and medical advisors that particular physicians were engaged in "continuous prescribing to patients known to be trafficking in Suboxone/Subutex;" allowing "prescriptions [to be] given when provider not present in office;" "charg[ing] 400 per month" for prescriptions; and suspected of allowing "overt trafficking in provider's parking lot."

101. INDIVIOR executives were aware of the careless, clinically unwarranted prescribing. On or about July 22, 2009, INDIVIOR's chief executive officer wrote to INDIVIOR's vice president for clinical affairs, "I think that the process for reporting rogue physicians is going to be very important." On or about July 14, 2010, INDIVIOR executives met and discussed data indicating that the 564 highest-prescribing physicians in the United States prescribed buprenorphine-containing drugs to an average of more than 200 patients at a time, and the highest prescribers, which INDIVIOR called "Super P8s," accounted for 33% of INDIVIOR's business.

102. INDIVIOR continued to include physicians it knew were issuing careless, clinically unwarranted opioid prescriptions in the Here to Help and Treatment Advocate programs, and otherwise market Suboxone Film to them. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctor A, located in or around Cedar Bluff, Galax, and Willis, Virginia, to switch prescriptions to Suboxone Film where Doctor A exceeded the maximum number of patients allowed at a time,

where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:[5]

Par.	Date(s)	Personnel	Information
103	7/17/2008	INDIVIOR Risk Mgr. to INDIVIOR Med. Advisor	Email: INDIVIOR Risk Mgr. suspected that Doctor A's clinic was one of two possible sources of "1 to 2 controlled buys of Suboxone per week" by law enforcement
104	4/9/2009	INDIVIOR Risk Mgr. and others	Received statistical report: Doctor A prescribed buprenorphine-containing drugs to 805 individuals in February 2009, at daily doses higher than 24 mgs of buprenorphine to 428 of those individuals
105	8/28/2009	INDIVIOR Sales Spvsr. to INDIVIOR Risk Mgr.	Firsthand report: Doctor A intentionally mislabeled prescriptions for buprenorphine-containing drugs as being for pain management, when also prescribed for opioid addiction, to evade detection for violating the DATA patient limit
106	4/30/2010, 6/1/2011, 9/2/2011, 10/6/2011	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas
107	2011	INDIVIOR Sales Rep. to INDIVIOR Sales Spvsr.	Reports: met with Doctor A at least 28 times to encourage Doctor A to prescribe Suboxone Film
108	5/1/2012	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor A, using a list of enrolled prescribers in the patient's geographic area
109	5/10/2012	INDIVIOR Sales Rep. to INDIVIOR Med. Advisor	Email: successfully convinced Doctor A to switch to prescribing Suboxone Film, as "Basically I lived with [Doctor A] last fall, seeing her once or twice a week, every week, even Saturdays; and eventually it paid off and her share of tablet vs film completely flip flopped"
110	4/12/2013, 4/26/2013	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas
111	9/10/2013	INDIVIOR Sales Rep. to INDIVIOR Risk Mgr.	Firsthand report: Doctor A is "[m]assively over cap [the maximum patient limit allowed under the DATA] . . . she also overdoses. . . . This has been an ongoing problem since I started that only continues to get worse"
112	12/13/2013, 11/3/2014, 3/10/2015, 3/13/2015, 3/18/2015,	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas

[5] These are illustrative examples, not an exhaustive list.

	4/27/2015, 5/26/2015, 5/26/2015, 6/18/2015, 7/8/2015		

113. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctors B and C, located in or around Johnson City, Tennessee, to switch prescriptions to Suboxone Film where Doctors B and C exceeded the maximum number of patients allowed at a time, where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:

Par.	Date(s)	Personnel	Information
114	4/9/2009	INDIVIOR Risk Mgr. and others	Received statistical report: in March 2009, Doctor B prescribed buprenorphine-containing drugs to 650 individuals, at daily doses higher than 24 mgs of buprenorphine to 618 of those individuals, and Doctor C prescribed buprenorphine-containing drugs to 635 individuals, at daily doses higher than 24 mgs of buprenorphine to 272 of those individuals
115	4/9/2009	INDIVIOR Employee, INDIVIOR Med. Advisor, and INDIVIOR Sales Spvsr.	Email re statistical report: "Notice your favorite, [Doctor B], is still at the top. I think now you can feel much more certain that he is likely a big source of diversion – 95% (618) of his patients are over 24mg. Wow!" Email further discussing report: "It appears that the 'high' doses may be the contributing factor to the diversion that continues to be reported in the Tri-Cities area of SE KY, NE TN, and SW VA"
116	5/28/2009	INDIVIOR Risk Mgr. to INDIVIOR Exec.	Email: "I am concerned about the Tri-Cities area in northeast Tennessee (also includes southeast KY and southwest VA). Physicians are prescribing for too many patients and the dosing is very high in some circumstances. 14 treating over 200 patients – range 200 to 800. 8 of 14 are prescribing doses >24 mg for at least 50% of their patients"
117	7/6/2009, 12/14/2009, 12/18/2009	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor C, using lists of enrolled prescribers in the patients' geographic areas
118	2/3/2010	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor B, using a list of enrolled prescribers in the patient's geographic area

119	2/5/2010	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area
120	4/8/2010	INDIVIOR Sales Sprvsr. to INDIVIOR National Sales Sprvsr.	Email: Doctor B is "well over the allowed patient cap," and Doctor C's office "will prescribe to as many patients as they can fit in [while physicians are] in about 2-3 hours each week. In that time they quickly see the patient & provide a script"
121	6/2/2010	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area
122	11/20/2010	INDIVIOR Exec. to INDIVIOR Salespeople	Award: INDIVIOR sales rep. marketing Suboxone Film to Doctors B and C named Suboxone Film Marketing Blitz "Contest Winner" and credited with "incredible performance . . . 13 times the initial Contest patient threshold"
123	2010	INDIVIOR Exec. to INDIVIOR Salespeople	Award: INDIVIOR sales rep. marketing Suboxone Film to Doctors B and C recognized as INDIVIOR's sales rep. of the year
124	2010-2011	INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr.	Reports: met with Doctors B and C at least 75 times to encourage them to prescribe Suboxone Film
125	1/23/2012	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area
126	4/22/2013	INDIVIOR Sales Rep. and INDIVIOR Sales Sprvsr. to INDIVIOR Mgr.	Conversation: "It's a liability almost that we're even walking into these offices, these two main clinic offices [of Doctor C], because of how criminal it is. Like they have a Vegas-style cash machine sitting behind the office where they're taking stacks of hundreds and shoving it in there while we're trying to like, detail the nurse. It's like the mob. It's awful"
127	8/9/2013	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area

128. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctor D, located in or around Danville, Kentucky, to switch prescriptions to Suboxone Film where Doctor D exceeded the maximum number of patients allowed at a time, where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:

Par.	Date(s)	Personnel	Information
129	6/25/2008	INDIVIOR Sales Sprvsr. to INDIVIOR Sales Rep.	Coaching form: "Continue to Partner with [Doctor D's clinic] and their growing . . . organization. While it can appear the program is on auto-pilot, they still have much to learn, and we can help"
130	7/11/2008	INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr.	Report: "The 2nd [office of Doctor D's clinic] opened in Barboursville, the third one is scheduled to open in August and that will be in Frankfurt. The plan is to have 10 physicians in each clinic. Expanding trx in the South, one clinic at a time!"
131	12/17/2008	INDIVIOR Med. Advsr. to INDIVIOR Risk Mgr. and INDIVIOR Sales Sprvsr.	Email: Doctor D "is in difficulties with his organization of 30 MDs related to prescribing of Suboxone. This stems perhaps from a couple of problem patients and led to a state board investigation. Most of their patients are on 24 mg daily. . . . Is this group in Kentucky an area of concern for us? Is there any follow-up needed?"
132	7/23/2009, 8/13/2009, 8/31/2009	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas
133	9/23/2009	Doctor D to INDIVIOR Gov. Mgr. and INDIVIOR Sales Rep.	Email: "We are even more excited about the opportunities we have to facilitate each others' [sic] success. . . . We will keep our noses to the grindstone getting our program of care 'refined' and ask that you continue to keep your brain grinding on how to best 'use' us everywhere and any way it makes sense. We will keep [INDIVIOR] updated as we collaborate with Medicaid, private payors, the VA system, and anything/anyone else we come across. We are pursuing multiple grants as of yesterday evening for the call centerdatabase [sic]/website plan and indigent care for opiate addicts (those with no pay source), but if there is any way [INDIVIOR] can get involved financially, there will be great business benefit for [INDIVIOR] in the end (more patients being prescribed SBX) and amazing PR for each state you support"
134	9/23/2009	INDIVIOR Sales Sprvsr. to INDIVIOR Gov. Mgr.	Email: "We have had a difficult time giving [Doctor D] what he wanted, because most of his requests are out of pharma guidelines. . . . I can see you were able to provide him with opportunities and information that he sees as very valuable to his treatment center plans and goals. Thank you for helping [ensure Doctor D's clinic] sees the Integrated Value [INDIVIOR] has to offer"
135	1/4/2010, 5/13/2010, 5/17/2010, 9/7/2010, 9/30/2010, 10/19/2010, 10/26/2010, 11/10/2010	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas

136	12/8/2010	Doctor D to INDIVIOR Gov. Mgrs., INDIVIOR Sales Rep., and others	Report: in one month, Doctor D's clinic had prescribed buprenorphine-containing drugs to 1,659 individuals, at daily doses higher than 24 mgs of buprenorphine to 39% of them, and at daily doses of at least 24 mgs of buprenorphine to 76% of them. INDIVIOR's Public Sector Dir. forwarded the report to others at INDIVIOR, stating, "[w]ith over 76% of the patients at 24 mg and above, we have some serious work today in educating his organization and the physicians about dosing and overall quality care. The reverse should likely be the case"
137	12/23/2010, 1/5/2011, 1/10/2011, 1/28/2011, 3/25/2011, 4/21/2011, 4/22/2011, 5/5/2011, 5/11/2011, 5/16/2011, 5/17/2011, 5/25/2011, 6/8/2011, 6/27/2011, 8/12/2011, 8/15/2011, 8/19/2011, 9/15/2011, 10/3/2011, 10/19/2011, 11/4/2011, 11/30/2011	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas
138	2011	INDIVIOR Exec. to INDIVIOR Salespeople	Award: INDIVIOR sales rep. marketing Suboxone Film to Doctor D's clinic recognized as INDIVIOR's sales rep. of the year
139	2/2/2012	INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr.	Email: INDIVIOR to sponsor Doctor D's clinic's annual meeting, including breakfast and lunch for 46 people
140	2/13/2012, 2/16/2012, 3/7/2012, 4/9/2012, 4/18/2012, 5/2/2012, 5/16/2012	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas

141	6/4/2012	Kentucky Board of Medical Licensure	Indefinite restriction of Doctor D's authorization to prescribe buprenorphine-containing drugs for use in opioid addiction/dependence treatment
142	6/25/2012 through 12/2/2016	"Here to Help" telephone operators	About 140 instances in which Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas
143	3/31/2017	United States District Court for the Eastern District of Kentucky	Doctor D convicted of 17 counts of health care fraud

SUBOXONE TABLET PRICE INCREASES TO SUPPORT SCHEME

144. Between in or about 2010 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents also increased the price of Suboxone Tablet to cause patients to switch to Suboxone Film. In or about October 2011, an INDIVIOR manager told colleagues, "I could not support a tablet [price] increase again before next October. That would be essentially another 37% over 24 months. . . . If we are considering the patient in all of this, then we need to understand that 40% will have to remain on the tablet due to supply constraints. . . . We also need to consider the public health backlash and that of physicians." In or about July 2012, INDIVIOR increased the price of Suboxone Tablet by 15%, stating the "Rationale of Price Increase" as "accelerate conversion to Film."

REVENUE AND PROFIT

145. In or about the specified years, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) and Company A received approximately the following revenues from sales of Suboxone Film:

Year	Revenue
2010	$83,328,721
2011	$400,615,412
2012	$666,695,781

2013	$887,469,559
2014	$843,047,500

In or about the same years, Medicare and Medicaid payments for Suboxone Film were approximately as follows:

Year	Medicare	Medicaid
2010	$2,134,000	$7,136,000
2011	$26,188,000	$108,079,000
2012	$70,329,000	$211,294,000
2013	$132,984,000	$326,666,000
2014	$147,704,000	$386,685,000

146. In or about September 2012, Company A stated that it would give "special recognition awards" of thousands of shares of Company A stock to about ten INDIVIOR executives and managers for the commercial success of Suboxone Film, saying it had "created a long-term sustainable business model for" INDIVIOR.

147. On or about August 5, 2013, INDIVIOR's chief executive officer emailed Company A's chief executive officer and others, stating that Suboxone Film's share of the market had grown to 69.1%, which was "almost enough to make you wonder when we will break through the 70% share barrier?" Company A's chief executive officer replied-all, "I agree, our US team has done a fantastic job of defending our film share thus far."

148. On or about November 17, 2013, INDIVIOR's chief executive officer stated to an INDIVIOR manager that in switching physicians, pharmacists, health care benefit programs, and others to Suboxone Film, INDIVIOR had achieved "the best format conversion ever in the history of the industry."

COUNT ONE
Conspiracy to Commit Mail, Wire, and Health Care Fraud

The Grand Jury charges that:

1. The Introduction to this Indictment and the factual allegations of Counts Two through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury knowingly conspired to commit the following offenses:

a. Mail fraud, in violation of Title 18, United States Code, Section 1341, that is, having devised and intending to devise the scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises described in the Introduction to this Indictment, and for the purpose of executing such scheme and artifice and attempting to do so, did knowingly cause to be delivered by the Postal Service and any private or commercial interstate carrier certain matters and things according to the directions thereon;

b. Wire fraud, in violation of Title 18, United States Code, Section 1343, that is, having devised and intending to devise the scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises described in the Introduction to this Indictment, and for the purpose of executing such scheme and artifice and attempting to do so, transmitted and caused to be transmitted by means of wire communication in interstate commerce writings, signals, and sounds;

c. Health care fraud, in violation of Title 18, United States Code, Section 1347, that is, knowingly and willfully executed and attempted to execute the scheme and artifice to defraud and to obtain by means of materially false and fraudulent pretenses, representations, and promises money and property owned by and under the custody and control of Medicare, Medicaid, private insurance providers, and other health care benefit programs in connection with the delivery of and payment for health care benefits, items, and services, described in the Introduction of this Indictment.

3. In furtherance of the conspiracy, and to effect its object, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury committed the overt acts described in the Introduction to this Indictment, and Counts Two through Twenty-eight of this Indictment.

4. All in violation of Title 18, United States Code, Section 1349.

COUNT TWO
Health Care Fraud

The Grand Jury charges that:

1. The Introduction to this Indictment and the factual allegations of Counts One and Three through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, as principals and aiders and abettors, knowingly and willfully executed and attempted to execute a scheme and artifice to (1) defraud health care benefit programs as defined in Title 18, United States Code, Section 24(b), including Medicaid, Medicare, other public health care programs, private insurance providers, and other health care benefit programs, and (2) obtain by means of

materially false and fraudulent pretenses, representations, and promises, money and property owned by and under the custody and control of said health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services.

3. It was the object of the scheme and artifice to fraudulently induce physicians to write prescriptions for Suboxone Film, pharmacists to fill prescriptions for Suboxone Film, and health care benefit programs to provide coverage of prescriptions for Suboxone Film, and to cause:

a. Patients to obtain Suboxone Film from pharmacies and others;

b. Patients, pharmacies, and others to submit claims for Suboxone Film to health care benefit programs;

c. Health care benefit programs to pay claims for Suboxone Film;

d. Pharmacies and others to make payments to wholesalers, distributors, and others for Suboxone Film; and

e. Wholesalers, distributors, and others to make payments to INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) for sales of Suboxone Film made as a result of the scheme and artifice to defraud.

4. In furtherance of the scheme and artifice, and to effect its object, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, for the purpose of causing health care providers and others to prescribe and dispense Suboxone Film, and to recommend the prescribing and dispensing of Suboxone Film, did, and aided, abetted, counseled, commanded, induced, and procured others to, make materially false and fraudulent statements and representations, including the following:

a. Representing to physicians, pharmacists, and other health care providers that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, and has other unsubstantiated effects such as weeding out drug seekers, making patients feel less like addicts, protecting physicians from being criminally prosecuted, and protecting office-based treatment of opioid addiction/dependence from being banned;

b. Producing and disseminating printed marketing materials representing that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, containing misleading text, graphics, and charts;

c. Representing to government officials, employees, and agents administering various state Medicaid programs, and others, that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, to cause such government officials, employees, and agents, and others to expand and maintain Medicaid coverage of Suboxone Film at substantial cost to the government and substantial profit to the defendants; and

d. Providing patient referrals, presentations, marketing materials, access to lunch and dinner events, and other benefits to physicians they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than the maximum dose of any demonstrated additional clinical advantage (*i.e.*, 24 mgs of buprenorphine), and in a careless and clinically unwarranted manner.

5. All in violation of Title 18, United States Code, Sections 2 and 1347.

COUNTS THREE THROUGH SIX
Mail Fraud

The Grand Jury charges that:

1. The Introduction and the factual allegations of Counts One through Two and Seven through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, with the intent to defraud, devised and willfully participated in, with knowledge of its fraudulent nature, the scheme and artifice to defraud and obtain money and property by materially false and fraudulent pretenses, representations, and promises described in the Introduction and in the factual allegations of Counts One through Two and Seven through Twenty-eight of this Indictment.

3. On or about the date specified as to each count below, in the Western District of Virginia, for the purpose of executing and attempting to execute such scheme and artifice to defraud, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury caused to be delivered by mail and private or commercial interstate carrier according to the direction thereon, the named matter and thing, namely, marketing visual aids containing materially false and fraudulent representations that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, including misleading text, graphics, and charts, to an INDIVIOR sales representative in Roanoke, Virginia, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Blacksburg, Cedar Bluff, Charlottesville, Christiansburg, Danville, Galax, Lynchburg, Roanoke, Salem, Staunton, Willis, and Wytheville, Virginia:

COUNT	DATE
THREE	February 6, 2012
FOUR	January 4, 2013
FIVE	March 21, 2013
SIX	August 19, 2013

4. All in violation of Title 18, United States Code, Sections 2 and 1341.

COUNTS SEVEN THROUGH TWENTY-EIGHT
Wire Fraud

The Grand Jury charges that:

1. The Introduction and the factual allegations of Counts One through Six are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, with the intent to defraud, devised and willfully participated in, with knowledge of its fraudulent nature, the scheme and artifice to defraud and obtain money and property by materially false and fraudulent pretenses, representations, and promises described in the Introduction and the factual allegations of Counts One through Six of this Indictment.

3. On or about the date specified as to each count below, in the Western District of Virginia and elsewhere, for the purpose of executing and attempting to execute such scheme and artifice to defraud, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, caused to be transmitted by wire communication or radio communication in interstate and foreign commerce, writings, signs, signals, pictures, and sounds, namely, reports of clinical liaisons falsely and fraudulently representing to physicians, pharmacists, and other health care providers that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child

exposure than other, similar drugs, transmitted from Florida and New Jersey to locations in the Western District of Virginia, and referrals of prospective patients to Doctor A, transmitted from Pennsylvania to locations in the Western District of Virginia, as described below:

COUNT	DATE	ITEM
SEVEN	April 30, 2010	Referral to Doctor A
EIGHT	October 9, 2010	Activity Report with Model Safety Claims
NINE	October 24, 2010	Activity Report with Model Safety Claims
TEN	November 29, 2010	Activity Report with Model Safety Claims
ELEVEN	June 1, 2011	Referral to Doctor A
TWELVE	July 8, 2011	Activity Report with Model Safety Claims
THIRTEEN	September 2, 2011	Referral to Doctor A
FOURTEEN	October 6, 2011	Referral to Doctor A (1 of 2 on this date)
FIFTEEN	October 6, 2011	Referral to Doctor A (2 of 2 on this date)
SIXTEEN	May 1, 2012	Referral to Doctor A
SEVENTEEN	April 12, 2013	Referral to Doctor A
EIGHTEEN	April 26, 2013	Referral to Doctor A
NINETEEN	December 13, 2013	Referral to Doctor A
TWENTY	November 3, 2014	Referral to Doctor A
TWENTY-ONE	March 10, 2015	Referral to Doctor A
TWENTY-TWO	March 13, 2015	Referral to Doctor A
TWENTY-THREE	March 18, 2015	Referral to Doctor A
TWENTY-FOUR	April 27, 2015	Referral to Doctor A
TWENTY-FIVE	May 26, 2015	Referral to Doctor A (1 of 2 on this date)
TWENTY-SIX	May 26, 2015	Referral to Doctor A (2 of 2 on this date)
TWENTY-SEVEN	June 18, 2015	Referral to Doctor A
TWENTY-EIGHT	July 8, 2015	Referral to Doctor A

4. All in violation of Title 18, United States Code, Sections 2 and 1343.

NOTICE OF FORFEITURE

1. The Introduction and the factual allegations of Counts One through Twenty-Eight of this Indictment are realleged and made part of this Notice.

2. Upon conviction of one or more of the felony offenses alleged in this Indictment, INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) shall forfeit to the United States:

a. pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes, or is derived from proceeds traceable to a violation of any offense constituting "specified unlawful activity" (as defined in section 1956(c)(7)), or a conspiracy to commit such offense; and

b. pursuant to 18 U.S.C. § 982(a)(7), property, real or personal, that constitutes, or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

3. The property to be forfeited to the United States includes, but is not limited to, the following:

a. **Monetary Judgment:** Not less than $3,000,000,000 (three billion dollars) in United States currency and all interest and proceeds traceable thereto, in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

b. **Business Entities (including all assets, inventory, and property related thereto):** Indivior Finance (2014) LLC; Indivior Finance SARL; Indivior Global Holdings Ltd (a/k/a RBP Global Holdings Limited); Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.); Indivior PLC; Indivior Solutions Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Solutions Inc.); and Indivior US Holdings Inc. (f/k/a RBP US Holdings Inc.).

c. **Bank Accounts, all funds received and on deposit as set forth below:**

	Bank	Account Name	Account #
(1)	Bank of America	Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.)	[redacted]
(2)	JP Morgan Chase	Indivior Inc.	[redacted]
(3)	JP Morgan Chase	Indivior Inc.	[redacted]

(4)	JP Morgan Chase	Indivior Inc.	[redacted]
(5)	JP Morgan Chase	Indivior Solutions Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Solutions Inc.)	[redacted]
(6)	JP Morgan Chase	Reckitt Benckiser Pharmaceuticals Inc. - Catalyst /ASO CGLIC as ADMIN - ERISA Account	[redacted]
(7)	JP Morgan Chase	Reckitt Benckiser Pharmaceuticals Inc. - Catalyst /ASO CGLIC as ADMIN - ERISA Account	[redacted]
(8)	JP Morgan Chase (Great Britain)	Indivior PLC	[redacted]
(9)	JP Morgan Chase (Great Britain)	Indivior PLC	[redacted]
(10)	JP Morgan Chase (Great Britain)	Reckitt Benckiser Pharm Inc.	[redacted]
(11)	Wells Fargo	Indivior Inc.	[redacted]
(12)	Institutional Cash Distributors (ICD), LLC	Indivior PLC	

d. **Trademarks:**

	Serial No., Registration No.
(1)	86779039
(2)	86779033
(3)	86779029
(4)	86779026
(5)	79151424, 4718643

e. **Patents:**

	Patent Number	Patent Title
(1)	8,475,832	Sublingual and buccal film compositions

(2)	8,497,280	Medicinal compositions comprising buprenorphine and nalmefene
(3)	8,697,718	Pack of medicinal tablets
(4)	8,912,211	Medicinal compositions comprising buprenorphine and naltrexone
(5)	8,921,387	Injectable flowable composition comprising buprenorphine
(6)	8,975,270	Injectable flowable composition comprising buprenorphine
(7)	9,101,625	Buprenorphine-wafer for drug substitution therapy
(8)	9,180,197	Sustained delivery formulations of risperidone compounds
(9)	9,186,413	Sustained delivery formulations of risperidone compounds
(10)	9,272,044	Injectable flowable composition buprenorphine
(11)	9,370,512	Buprenorphine-wafer for drug substitution therapy

4. If any of the above-described forfeitable property, as a result of any act or omission of the defendant, cannot be located upon the exercise of due diligence; has been transferred or sold to or deposited with a third person; has been placed beyond the jurisdiction of the Court; has been substantially diminished in value; or has been commingled with other property which cannot be subdivided without difficulty; it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above described forfeitable property pursuant to 21 U.S.C. § 853(p), including the assets described above, and including but not limited to the following assets:

a. **Accounts Receivable, all amounts due from the following entities:**

(1)	Amerisource Bergen
(2)	Burlington Drug
(3)	Cardinal Health
(4)	Dakota Drug Inc
(5)	Dixon Shane LLC

(6)	Harvard Drug Group
(7)	HD Smith
(8)	Integrated Commercialization Solutions
(9)	JM Smith
(10)	Luis Garraton
(11)	McKesson
(12)	Morris Dickson
(13)	MWI Vet Supply
(14)	NC Mutual Drug Company
(15)	Rochester Drug
(16)	Valley Wholesale
(17)	Value Drug Company

A TRUE BILL, this 9th day of April, 2019.

/s/ Grand Jury Foreperson

by Randy Ramezzo
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EXHIBIT 2

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Case No.** 1:19CR00016
	)	
INDIVIOR INC. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and INDIVIOR PLC	)	**Violations:** **18 U.S.C. §§ 2, 1341, 1343, 1347, 1349**

SUPERSEDING INDICTMENT

OVERVIEW

The Grand Jury charges that:

1. Suboxone Film is an opioid drug used in the treatment of opioid addiction/dependence. Indivior sells Suboxone Film throughout the United States. Beginning in or about 2010, Indivior executed an illicit nationwide scheme to increase prescriptions of Suboxone Film. In particular, Indivior illegally obtained billions of dollars in revenue from Suboxone Film prescriptions by deceiving health care providers and health care benefit programs into believing that Suboxone Film is safer and less susceptible to diversion and abuse than other, similar drugs. Indivior further sought to boost its profits from Suboxone Film by establishing a telephone program for patients to call to be connected with a doctor for opioid addiction/dependence treatment, which Indivior used to connect patients to doctors Indivior knew were prescribing Suboxone and/or other opioids in a careless and clinically unwarranted manner. Indivior's fraudulent scheme lasted for years and hindered patients', health care providers', and health care benefit programs' accurate assessments regarding opioid-addiction treatment in order to increase the company's profits.

INTRODUCTION

The Grand Jury charges that at times material to this Indictment:

DEFENDANTS

2. INDIVIOR INC. (hereinafter "INDIVIOR") was a Delaware corporation headquartered in Richmond, Virginia, that marketed and distributed prescription drugs containing buprenorphine, an opioid controlled substance, under brand names including Suboxone and Subutex. Until on or about December 23, 2014, INDIVIOR was a wholly owned subsidiary of Company A, and was known as Reckitt Benckiser Pharmaceuticals Inc.

3. INDIVIOR PLC was an English public limited company headquartered in Slough, England, United Kingdom, that owned, controlled, managed, and operated INDIVIOR after on or about December 23, 2014.

HEALTH CARE BENEFIT PROGRAMS

4. Medicare was a health care benefit program under Title 18, United States Code, Section 24(b) that provided basic medical coverage to individuals age 65 or older and to certain disabled persons. The United States Department of Health and Human Services, through the Centers for Medicare and Medicaid Services ("CMS"), administered Medicare through contractors. Medicare Part D paid for certain prescription drugs for Medicare beneficiaries.

5. Medicaid was a health care benefit program under Title 18, United States Code, Section 24(b) that was administered by agencies of the various states to provide health care benefits and services to those who qualified. Medicaid was funded jointly by the states and by CMS and paid for certain prescription drugs for Medicaid beneficiaries.

6. Other public health care programs and private health care insurance providers were health care benefit programs under Title 18, United States Code, Section 24(b) that paid for certain prescription drugs for their beneficiaries.

LEGAL AUTHORITY

7. The Federal Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 301, *et seq.*, provided that no drug could be marketed in interstate commerce unless it had been approved by the Food and Drug Administration ("FDA").

8. The Orphan Drug Act ("ODA"), Title 21, United States Code, Sections 360aa, *et seq.*, provided that the FDA could designate a drug as an "orphan drug," and upon approving the drug, would not approve another drug for the same disease or condition for seven years.

9. The Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), Title 21, United States Code, Section 355(j), provided that the FDA could approve generic drugs without requiring all of the clinical testing required for new drugs.

10. The Drug Addiction Treatment Act ("DATA"), Title 21, United States Code, Section 823(g), authorized registered health care providers to prescribe certain opioid drugs in Schedules III, IV, or V of the Controlled Substances Act ("CSA"), Title 21, United States Code, Section 801, *et. seq.*, for the treatment of opioid addiction/dependence outside a treatment clinic. The DATA limited the maximum number of patients a provider could so treat at any one time. Through in or about July 2016, the maximum limit for any one provider was 100 patients at a time. In or about August 2016, the maximum limit was raised to 275 patients at a time.

11. Title 21, Code of Federal Regulations, Part 1306.04, stated that a prescription for a controlled substance was effective only if issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.

SUBOXONE TABLET AND SUBUTEX TABLET

12. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continued taking opioids under medical supervision, to avoid or reduce withdrawal symptoms while they sought to recover. The only opioid approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take home) was buprenorphine, a Schedule III controlled substance under the CSA.[1]

13. On or about October 8, 2002, INDIVIOR received FDA approval of the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet ("Suboxone Tablet") and Subutex Sublingual Tablet ("Subutex Tablet"). The FDA designated both as orphan drugs, meaning the FDA committed not to approve any competitor drug for seven years (the "exclusivity period").

14. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Daily doses of Suboxone Tablet containing more than 24 milligrams ("mgs") of buprenorphine were not shown to provide any clinical advantage over lower doses. Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps. Before in or about 2013, another subsidiary of Company A manufactured Suboxone Tablet in Hull, England, United Kingdom, and INDIVIOR marketed and distributed it throughout the United States.

[1] Buprenorphine is an opioid partial agonist with a morphine milligram equivalent conversion factor ("MME-CF") 20 times higher than oxycodone.

15. Subutex Tablet was similar to Suboxone Tablet, but did not include naloxone. It was intended for certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps. Before in or about 2011, another subsidiary of Company A manufactured Subutex Tablet in Hull, England, United Kingdom, and INDIVIOR distributed it throughout the United States.

SUBOXONE FILM AND THE PLAN TO MARKET IT

16. By in or about 2007, INDIVIOR's and Company A's annual revenue from sales of Suboxone Tablet and Subutex Tablet had grown to more than $260 million, but they forecast they would lose most of that revenue to competitor drugs, particularly generic versions of Suboxone Tablet, after the exclusivity period ended on October 8, 2009.

17. Between in or about December 2006 and March 2007, INDIVIOR and Company A began developing a new buprenorphine-containing drug for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Film ("Suboxone Film"). They believed Suboxone Film would be protected by patents. They planned to promote Suboxone Film by claiming it was safer than alternative drugs such as tablets, though there were no scientific studies to establish that claim.

18. Additionally, between in or about December 2006 and March 2007, INDIVIOR, Company A, and others discussed ways to delay FDA approval of generic versions of Suboxone Tablet by discontinuing Suboxone Tablet under the pretext of a safety concern, thereby triggering FDA safety-related processes that could take as long as a year. They wrote, "We could tie up generic for 1 year . . . . When we file for film and withdraw tablet [the FDA] is precluded from approving another tablet until they have made a determination in response to a petition from generic company to determine that product was not withdrawn for safety or

efficacy;" a "negative safety issue" could "prevent approval of generic;" "We need to think creatively about a safety story;" "we probably also need to think very negatively about [tablets] and identify aspects that could be unsafe;" "We cannot prevent generics . . . We can delay;" and a timeline for how long generics could be delayed.

19. On or about October 20, 2008, INDIVIOR submitted a new drug application ("NDA") for Suboxone Film to the FDA. (INDIVIOR did not seek approval of a film version of Subutex.)

20. Like Suboxone Tablet, Suboxone Film contained buprenorphine and naloxone, was intended to be taken by placement under the tongue until dissolved, and daily doses containing more than 24 mgs of buprenorphine were not shown to provide any clinical advantage over lower doses. However, Suboxone Film differed from Suboxone Tablet in that it had a thin form; stuck to the tongue/mouth; dissolved more rapidly; potentially had higher bioavailability at certain doses; was formulated to taste better; and typically was dispensed by pharmacies in individually wrapped, child-resistant foil pouches each bearing a serial number.

21. Between in or about May 2009 and August 2010, while awaiting FDA approval of Suboxone Film, INDIVIOR managers drafted marketing plans for the drug. The draft plans listed "Key Success Drivers" for Suboxone Film such as "Driving physician prescriptions for Suboxone film," "Driving formulary support for Suboxone film through payors," and "Driving patient Suboxone film trial," and included the messages that Suboxone Film was "a more responsible medication from a public health perspective," was a "less divertible/abusable formulation," and had a "lower risk of child exposure," and that generic drugs would "jeopardize the entire disease space," though there were no scientific studies to establish these claims. The draft plans noted that public health care benefit programs such as Medicare, Medicaid, and the

Veterans Administration paid for 27% of all Suboxone Tablet and Subutex Tablet prescribed, while private health care benefit programs paid for 55%.

22. On or about June 9, 2009, INDIVIOR's medical director told fellow INDIVIOR medical personnel, "We need to develop a story about childhood exposures to set the stage for switching patients to" Suboxone Film.

23. On or about August 21, 2009, the FDA declined to approve INDIVIOR's NDA for Suboxone Film because it did not contain an adequate risk evaluation and mitigation strategy ("REMS") to address the FDA's concerns about misuse, abuse, and accidental overdose.

24. On or about October 5, 2009, INDIVIOR sent a letter to the FDA, asking whether the FDA agreed that Suboxone Film's packaging would protect against diversion (*e.g.*, illegal selling, sharing, and smuggling of Suboxone) and accidental child exposure (*i.e.*, children taking Suboxone by accident). The FDA did not immediately respond. INDIVIOR executives and others internally discussed that the FDA could disagree, for reasons including that it was not clear how physicians would use the serial numbers on Suboxone Film packages to deter diversion, and "there is an incremental risk of the film since once a child ingests the film it will be nearly impossible to remove vs. tablets."

25. On or about November 24, 2009, INDIVIOR resubmitted its NDA for Suboxone Film to the FDA, including a REMS.

26. On or about January 22, 2010, INDIVIOR's chief executive officer told Company A executives, "Our immediate focus is to get the FDA approval for [Suboxone Film] asap to switch the business ahead of the generic."

27. On or about March 29, 2010, the FDA responded to INDIVIOR's October 5, 2009 letter that sought the FDA's agreement that Suboxone Film's packaging would protect against diversion and accidental child exposure, stating:

> The Agency will not comment on whether the serial numbers [on Suboxone Film's packaging] would lead to a decrease in diversion of a drug product, because drug diversion issues are regulated by DEA.
>
> * * *
>
> No, we do not agree that the packaging for [Suboxone Film] provides meaningful incremental protection against pediatric exposure. Although the foil pouches fulfill the child resistant effectiveness standards and the foil pouch bears warning statements alerting patients to keep out of reach of children, no data were provided to support that these measures will encourage patients to store [Suboxone Film] in a manner which prevents accidental pediatric ingestion. Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial doses that are neither in the child-resistant pouch nor in a child-resistant medication bottle. Furthermore, because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.

28. INDIVIOR executives, managers, and personnel understood from the FDA's response that they lacked substantiation to inform health care providers that Suboxone Film was safer than alternative drugs such as tablets. INDIVIOR executives and managers wrote to each other, "The FDA has stated that we have no proof that patients will not take the film out of the [pouch] and cut it into multiple doses. Thus not reducing potential exposure . . . . Even then the FDA points out that the film may not be swallowed thus making more buprenorphine available;" that the FDA's response could "be a bigger issue as it may imply the overall risk/benefit is not favorable for our film (vs tablet);" and, "It looks like they are trying to deny us the ability to make a claim on additional paediatric safety of the film." With regard to misuse, abuse, and

diversion, INDIVIOR executives, managers, and personnel knew that Suboxone Film's thin form potentially could make it easier to conceal, and thus more susceptible to smuggling than tablets; its individual packaging could make it more portable, including for reselling and sharing; and the serial numbers on the pouches were not electronically tracked and not shown to deter diversion. With regard to accidental child exposure, they knew that Suboxone Film had attributes that potentially could make it more dangerous to children, including that it stuck and could not easily be spit out if accidentally taken by a child; dissolved more rapidly, leaving less time to remove it from a child's mouth before absorption; had potentially higher bioavailability at certain doses, potentially increasing the severity of an incident; was formulated to taste better, potentially reducing the likelihood that a child would seek to remove it; and could not easily be re-secured in its original packaging, which, unlike a bottle with a child-resistant cap, was not designed to be re-closed.

29. On or about August 30, 2010, the FDA approved Suboxone Film, including the REMS and prescribing information for the drug. None of these materials stated that Suboxone Film was safer than alternative drugs such as tablets, or reduced the risk of misuse, abuse, diversion, or accidental child exposure. Nevertheless, INDIVIOR's chief executive officer told Company A executives including its chief executive officer and chief financial officer, "We will be making the most of every minute between now and generic approval to convert our tablet business to film," including a "Full Blitz campaign for salesforce through Thanksgiving." For the full blitz campaign, INDIVIOR salespeople planned to raise "diversion and misuse and pediatric safety" in sales presentations to physicians, even though there were no scientific studies to establish that Suboxone Film was safer with regard to diversion, misuse, or pediatric safety.

30. Suboxone Film was manufactured by another subsidiary of Company A in Hull, England, United Kingdom, and a third party in Portage, Indiana. INDIVIOR marketed and distributed it throughout the United States.

THE SCHEME AND ARTIFICE TO DEFRAUD

31. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents did devise and intend to devise a scheme and artifice to defraud and to obtain money and property from health care benefit programs by means of materially false and fraudulent pretenses, representations, and promises, by (A) making materially false and fraudulent statements and representations to health care providers to induce them to prescribe, dispense, and recommend Suboxone Film; (B) preparing and causing to be prepared, and shipping and causing to be shipped, materially false and fraudulent marketing materials promoting Suboxone Film; (C) making materially false and fraudulent statements and representations to and relating to state Medicaid administrators and others to promote Suboxone Film; and (D) marketing Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner.

A. MATERIALLY FALSE AND FRAUDULENT STATEMENTS AND REPRESENTATIONS TO HEALTH CARE PROVIDERS

32. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, materially false and fraudulent statements and representations to health care providers to induce them to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film.

33. On or about September 2, 2010 (about three days after Suboxone Film received FDA approval), Company A's chief executive officer emailed approximately 20 INDIVIOR executives and managers, including INDIVIOR's chief executive officer and marketing personnel, stating that Suboxone Film was "safer," and encouraging them to "convert [patients] from tablets to films, thereby protecting our Net Revenues in the USA."

34. On or about September 6, 2010 (about a week after Suboxone Film received FDA approval), an INDIVIOR national sales supervisor emailed approximately 50 INDIVIOR salespeople, encouraging them to tell physicians that Suboxone Film was "safer because of the packaging."

35. On or about October 17, 2010, INDIVIOR's chief executive officer told INDIVIOR personnel to revise the performance appraisals and incentive programs for salespeople to reward "film sales only." He stated that INDIVIOR's salespeople had "every possible resource to enable them to generate demand for a scheduled narcotic that is being given away for free to an addicted population," and those without "adequate film sales" may be fired. Thereafter, INDIVIOR revised the performance appraisals and incentive programs to be based primarily on the percentage of Suboxone Film compared to tablet sales in the salesperson's territory (sometimes called the "film market share" or "film share").

36. On or about October 25, 2010, INDIVIOR sales supervisors discussed baseless "dialogue points" that INDIVIOR salespeople were using to highlight Suboxone Film's "advantages" to physicians and pharmacists, which included "Reduced misuse/diversion" and "Public safety – reduced pediatric exposure." On or about November 3, 2010, an INDIVIOR sales supervisor emailed the dialogue points to INDIVIOR's chief executive officer.

37. In or about December 2010, INDIVIOR's vice president for clinical affairs met with physicians in California and elsewhere, and in the presence of INDIVIOR salespeople, materially falsely and fraudulently stated to the physicians that Suboxone "Film addresses child safety and abuse and diversion" and was a "safer product."

38. On or about February 14, 2011, an INDIVIOR national sales supervisor instructed a regional sales supervisor in Michigan and a sales representative in Ohio to:

> not be afraid to let the physician know very clearly what you believe. If you believe that Suboxone Sublingual Film will lower pediatric exposure, or lower diversion and misuse let them know. You are the expert and because of all you have done, the relationships you have built, they will be receptive to what you believe.

39. On or about March 11, 2011, Company A's chief executive officer materially falsely and fraudulently stated in Company A's public 2010 annual report that Suboxone Film was "better from a child safety point of view, mak[ing] it more attractive for doctors to prescribe."

40. On or about April 13, 2011, INDIVIOR's chief executive officer materially falsely and fraudulently stated in a corporate newsletter that Suboxone Film "has the potential for greater child safety."

41. In or about July 2012, at a Company A investor presentation, in the presence of Company A's chief executive officer, INDIVIOR's chief executive officer materially falsely and fraudulently stated that Suboxone Film was "less divertable and abusable."

42. On or about the specified dates, in or around the specified states, INDIVIOR sales representatives reported to their supervisors and their fellow sales representatives to use as models for promoting Suboxone Film, the below-described statements and representations made to physicians, pharmacists, and other health care providers to materially falsely and fraudulently

induce them to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film:[2]

Par.	Date	State	Report
43	9/1/2010	NY	INDIVIOR sales representative told physicians that Suboxone Film "offers increased protection against misuse/abuse/diversion and pediatric exposure. Due to this, and the fact that patients will be able to get the film at no cost, they have all stated that they will prescribe the Film when it is available. . . . Most pharmacists have also been impressed with the new formulation and the steps the company has taken to decrease diversion and pediatric exposure"
44	9/10/2010	NC	INDIVIOR sales representative told a physician that Suboxone Film "offers greater protection against pediatric exposure & misuse/diversion"
45	9/30/2010	SC	INDIVIOR sales representative met with a physician and "[d]iscussed pediatric exposure & tablet diversion as reasons for MD to insist that pts switch from tablet to film"
46	12/16/2010	MI	INDIVIOR sales representatives told physicians that Suboxone Film is the "safest choice;" has "less chance of inadvertent use by kids," can "protect the community;" and can "protect office-based treatment" from being banned
47	12/21/2010	CA	INDIVIOR sales representative told physicians that Suboxone Film "is a better safer medication" and "it would be unethical or inappropriate for us to promote the tablet now that we have a better, safer product"
48	12/22/2010	MI	INDIVIOR-paid speaker told physicians that her "big plus for the Film was the packaging and therefore making it a safer product for the community"
49	12/22/2010	TN	INDIVIOR sales representative told physicians that during the holiday season, Suboxone Film gives patients "added comfort in knowing their medication is safer to have in the home as family and friends with small children will be visiting more"
50	1/6/2011	MI	INDIVIOR sales representative met with a physician who was "in the category of trying out the film but not yet sold on it," and stated that "it's important [for the physician] as a physician and mom to convert patients to the Film. The fact that film helps to protect [office-based opioid treatment] and reduces pediatric exposure appeared hard to ignore for the doctor. Hopefully that message will have a louder voice in her head than the patients telling her they are 'happy' with the Tablet"
51	1/11/2011	CA	INDIVIOR sales representative told physician and pharmacists that Suboxone Film is a "safer product vs tablet"
52	2/3/2011	IN	INDIVIOR sales representative told a physician that patients who request tablets do so "in order to divert them. [The physician] said that he may have become a bit too trusting in his several years of treat[ing] patients. We spoke about how the Film can 'weed out' those patients truly not committed to recovery. He promised to convert ALL patients to Film"
53	2/3/2011	UT	Physicians told an INDIVIOR sales representative that patients were "complaining about the Film and asking to be put back on the tablet." INDIVIOR sales

[2] These are illustrative examples, not an exhaustive list.

			representative responded by discussing "misuse and abuse of Suboxone tablets and how the Film is the better, safer choice. I know that we will have more followup in this office, due to these doctors' new awareness of what is really happening when some ask to be switched back to the tablet"
54	2/9/2011	TX	INDIVIOR sales representative told physicians "that many other doctors are going 'film only' because they want to provide the best quality care to their patients with the most efficacious, safest, and cost saving treatment and it has influenced several of them and they then have been interested in how others are doing this, how patients are responding, etc. I believe it makes them feel more confident to know that others are doing this and it also makes them want to do the same to keep up with 'quality care' physicians"
55	3/2/2011	TX	INDIVIOR sales representative told physicians that Suboxone Film is "newer, easier, quicker and most importantly safer for the patients and their families, the physicians and community"
56	3/2/2011	IN	INDIVIOR sales representative met with a pharmacist and "had a candid discussion as to why some patients want so badly to stay on the tablet even at a higher price to them (diversion). [The pharmacist] is going to 'hammer away' at [doctors who prescribed tablets] to get these patients on Film"
57	4/13/2011	IL	INDIVIOR sales representative told a physician and a pharmacist about "some of the blogs I have read and about the reported child death. This seemed to really impact them, and [the physician] said he has had some concern about a few patients in the past. We discussed that while the film cannot stop misuse and diversion, it can help prevent it, and our hope is to decrease the misuse and diversion, as well as the number of pediatric exposures. The pharmacist in the building also attended the [presentation] and everyone agreed that if a patient came to the pharmacy with a prescription for the tablet, the pharmacist would call back the office to see if it could be switched to film"
58	4/14/2011	CA	INDIVIOR sales representative told a physician that Suboxone Film is "safer, better, and cheaper than the pills. What reason do you have not to convert all of your patients to the film? She could not give a reason. She said she will switch her patients"
59	5/10/2011	CA	INDIVIOR sales representative told a physician that she would not help the physician enroll in a patient-referral program "unless I knew those patients seeking treatment would get a Comprehensive approach that includes the Safest Medication on the Market for Opioid Dependency which is the Film"
60	5/26/2011	UT	INDIVIOR sales representative told physicians that Suboxone Film is "safer to have around their family members"
61	6/8/2011	VA	INDIVIOR sales representative told physicians that one doctor in the area "converted all patients to Film and no longer give[s] a choice [between tablets and film] due to rampant diversion of the tablet in the area, which borders Virginia, Kentucky and Tennessee. This has been a great win and is something that I've been able to tell all my other docs who have converted most of their patients but not all"
62	7/7/2011	NC	INDIVIOR sales representative met with a physician who was "still giving [some] patients the choice between the Suboxone Film and tablet . . . . I strongly encouraged [the physician] to protect herself, her practice and her medical license

			by prescribing Suboxone film to ALL of her patients. I said, 'I don't want any of my physicians to find themselves on a witness stand defending their decision for prescribing Suboxone tablets which caused the death of a child.' Hopefully that statement convinced [the physician] to adopt a fail first policy on the Suboxone film"
63	7/7/2011	OR	INDIVIOR sales representative asked a physician what was "holding [him] back from the patient-preferred Film?" The physician stated that his "tablet patients are doing well and are afraid of changing when they are doing well." The INDIVIOR sales representative then "talked about Tablet exposures to children and how [the physician] can be their safety net by prescribing the Film rather than the Tablets which he agreed with"
64	7/7/2011	CA	INDIVIOR sales representative was "working diligently with [a physician] in order to get him to transition his considerable amount of tablet patients to the Film. I am making progress with him. He's been reluctant and has allowed his patients the choice [between tablets and film]. I believe I've instilled in him the importance of protecting public safety and [office-based opioid treatment], and how, by prescribing the Film, he will help to make that happen"
65	7/18/2011	PA	INDIVIOR sales representative "had an excellent conversation with [physicians] around more of the reasons why [they] might want to move more of their patients off of tablets and onto the Film. They agreed it was a safer option and are proud they are doing their part to protect our community"
66	7/21/2011	DE	INDIVIOR sales representative met with physicians and pharmacists, "capitalizing on the Public Health Message and the importance of providing patients with a safer option in the film"
67	7/21/2011	PA	INDIVIOR sales representative told physicians, "You get the same clinical efficacy [with Suboxone Film] as you get with tablets, possibly greater compliance with improved taste and dissolve time, safety is improved within the public and the home, and most patients get the Film for virtually free with the Savings program. Why take the chance?"
68	9/2/2011	MD	INDIVIOR-paid speaker told physicians that Suboxone Film was "preventing pediatric death in graphic terms"
69	10/26/2011	TN	INDIVIOR sales representative "led physicians to the internet so that they may see how their decisions to prescribe any tablet over [Suboxone Film] may have a negative impact on the community. There are current articles that [the tablet] kills children all over the internet and this helps them to see the reasons to prescribe [Suboxone Film] over the tablets. . . . One of my doctors . . . still has not converted all of his patients to [Suboxone Film]. He was able to visit the internet article to see how [Suboxone Film] could put safe guards in the community as well as in his practice. Once he saw this information he committed to write all of the [tablet] patients [Suboxone Film]. From the look on his face [he] was really concerned about the safety of his patients"
70	11/11/2011	VA	INDIVIOR sales representative made the following presentations to physicians: "The physicians agree that we all have an obligation to protect the public health. I have each physician [say] if they agree that it starts with THEM, the prescriber? They do agree. Then WHY would you not prescribe the SAFEST medication available? Is it worth the risk of pediatric exposure? Is it worth the risk of abuse

			and diversion? Is it worth the risk of ending office based treatment? It starts with YOU, DOCTOR! Unfortunately, it does NOT end with you! It can end with unintended consequences in the hands of people suffering from a terrible disease, who are not known for making the best decisions! These discussions have really opened the eyes of quite a few physicians who now realize their obligation." INDIVIOR sales supervisor singled out this presentation as a model presentation, forwarding it to other INDIVIOR salespeople
71	12/5/2011	IL, IN, KY, MI, OH, TN, WV	INDIVIOR sales representative collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone Film from others across the region, including "Baby Death articles;" "Diversion with Tablets and high street value of $25.00 per pill;" "Film harder to sell on streets;" "if patients call office and ask if doctor writes the tablets (or pills) that is a patient you do not want—they will be diverting and your office can or will be tied to that illicit drug;" "I inform my doctors (and pharmacists) that insurance companies are beginning to view the film the same way we do . . . as the superior (safer) product;" "I focus on the safety for their office as well as the general public, the fact [Suboxone Film] will weed out the drug seekers and it will make their offices respectable and full of patients who are serious about their recovery;" and "Patients are tempted to share especially when they are doing well and want to help people that they care about . . . . [Suboxone Film] will reduce this possibility"
72	2011	AZ, CA, CO, LA, MO, OR, TX, UT	INDIVIOR sales representatives collected "best practices" for convincing doctors, pharmacists, and others to switch patients to Suboxone Film from others across the region, including "Once the dialogue opens up about community, safety etc, I explain that we believe [Suboxone Film] is the safest medication available;" "[by] providing the safest medication (FILM) you (physician, pharmacist, counselor, office staff) are helping the patient 'close the gaps' in their treatment as well as reducing the chance of misuse, abuse and diversion, which increases public safety;" "Do you agree the Film is safer and less abusable than the tablet?;" "[Suboxone Film is] a safer alternative to the tablet – safer for the patients, safer for their families and more aligned with [INDIVIOR's] goal to protect office-based treatment;" and asking physicians "to imagine how devastated [their] patients would be if one of those children were to get into a bottle full of Suboxone tablets"

73. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents knew that messages like those described in paragraphs 33-72 of the Introduction to this Indictment materially influenced health care providers to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film. In or about January 2011, an INDIVIOR contractor reported to INDIVIOR executives, managers, and personnel that in a survey of 245 physicians who had

prescribed Suboxone Film, 68 physicians (approximately 28%) stated that they did so because it "[d]ecreases misuse/abuse/diversion," and 26 physicians (approximately 11%) stated that they did so for "[s]afety re: inadvertent use by children." Additionally, the physicians rated "Ability to minimize unintentional pediatric exposure" and "Reduces the likelihood of misuse & diversion" as the second and third leading reasons to prefer Suboxone Film, respectively.[3] More than 80% of the physicians, and 98% of the high-prescribing physicians, stated that they learned about Suboxone Film from INDIVIOR salespeople.

74. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents knew that the messages described in paragraphs 33-72 of the Introduction to this Indictment, and others like them, were false and fraudulent. In addition to the FDA's letter of March 29, 2010, informing INDIVIOR that it lacked substantiation to claim that Suboxone Film better protects against accidental child exposure (discussed above), on or about June 30, 2011, an INDIVIOR contractor reviewing information as part of the Suboxone Film REMS told INDIVIOR that Suboxone Film was more frequently abused parenterally (*e.g.*, by injection) and involved in more accidental child exposures per million doses than Suboxone Tablet. INDIVIOR did not alert patients, physicians, pharmacists, health care benefit programs, or others to these findings, which cast doubt on INDIVIOR's promotional messages about Suboxone Film. Subsequently, between in or about December 2011 and February 2012, INDIVIOR's compliance committee determined that INDIVIOR salespeople's written reports of their promotional statements to physicians and pharmacists (examples of which are set forth in paragraphs 43-72, above) posed "compliance risks," and discontinued the reports, without contacting patients, physicians, pharmacists, health

[3] "Speed of dissolving" was first.

care benefit programs, or others to correct or retract the promotional statements reflected in the reports. In or about November 2012, INDIVIOR's medical director, vice president for clinical affairs, and others discussed attributes of Suboxone Film that potentially could make it more dangerous to children, such as that, "With a tablet, they've got options. They can spit it out. They can swallow it. With the film, not necessarily. We know, it's stuck" in the child's mouth.

75. In or about 2012-13, INDIVIOR managers discussed that, "Under no circumstances can we make the claim that Suboxone Film is safer or better at reducing pediatric exposures," and "Saying Suboxone Film is safer than any tablet on the market because Film has less ability to be snorted/injected [is an] unsubstantiated superiority claim," but did not contact patients, physicians, pharmacists, health care benefit programs, or others to correct or retract the promotional statements INDIVIOR salespeople had already made.

B. MATERIALLY FALSE AND FRAUDULENT MARKETING MATERIALS PROMOTING SUBOXONE FILM

76. Between in or about 2010 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents prepared and caused to be prepared, and shipped and caused to be shipped by mail and private or commercial interstate carrier to their executives and employees and others throughout the United States, written marketing materials used to promote Suboxone Film that contained materially false and fraudulent statements and representations, including the following:

a. Suboxone Film was "Helping Address Public Health Needs;"

b. Suboxone Film could "Help Address Misuse and Abuse;"

c. Suboxone Film "Can Be Part of the Solution" to "misuse," "diversion and abuse," and "unintentional pediatric exposure;"

d. "Nearly half of Suboxone Film prescribers surveyed cited 'potential for reduction of abuse and diversion' as a reason to prescribe vs Suboxone Tablet," when in fact, only 28% of the prescribers had cited that supposed reason, many of them after receiving fraudulent sales presentations from INDIVIOR;

e. A false and fraudulent chart with the heading, "Suboxone Film—Helping to Reduce the Risk of Pediatric Exposure," that purported to depict pediatric exposure data for Suboxone Tablet and Suboxone Film, but intentionally omitted other data from the same study that showed that buprenorphine-only tablets also had low pediatric exposure, and therefore called into question the claim that Suboxone Film reduced pediatric exposure. An INDIVIOR employee asked INDIVIOR's medical director, "I couldn't help but notice that the chart did not show the [buprenorphine-only tablets] line. Does that mean we can also show the graph without [that] line? That would make such a huge difference!" INDIVIOR's medical director responded, "That chart is now published so nock [sic] yourself out!"

f. A false and fraudulent pair of charts with the heading, "Suboxone . . . Film—associated with lower rates of diversion and abuse . . ." that purported to depict diversion and abuse data for Suboxone Tablet, buprenorphine-only tablets, and Suboxone Film, but intentionally omitted two other charts from the same page of the same study that showed that Suboxone Tablet and buprenorphine-only tablets had diversion and abuse rates similar to Suboxone Film during certain time periods, and therefore called into question the claim that Suboxone Film was associated with lower rates of diversion and abuse.

77. On various dates, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents shipped and caused to be shipped by mail and private or commercial interstate carrier, copies of marketing materials described in paragraph 76 of the Introduction to this Indictment, from a contractor in New Jersey to sales representatives throughout the United States, including:

a. a sales representative in Roanoke, Virginia, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Blacksburg, Cedar Bluff, Charlottesville, Christiansburg, Danville, Galax, Lynchburg, Roanoke, Salem, Staunton, Willis, and Wytheville, Virginia, and

b. a sales representative in Greeneville, Tennessee, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Abingdon, Big Stone Gap, Bristol, Coeburn, Glade Spring, Lebanon, Marion, Norton, Pennington Gap, Pound, Saint Charles, Tazewell, and Wise, Virginia.

C. MATERIALLY FALSE AND FRAUDULENT STATEMENTS AND REPRESENTATIONS TO AND RELATING TO STATE MEDICAID ADMINISTRATORS AND OTHERS

78. Between in or about 2006 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, statements and representations that INDIVIOR was discontinuing the distribution of Suboxone Tablet due to safety concerns, when in fact, the reason for discontinuing the distribution of Suboxone Tablet was to delay the FDA's approval of generic versions of Suboxone Tablet.

79. Between on or about January 6, 2012, and September 14, 2012, INDIVIOR and Company A, knowing that potential competitors were preparing applications for FDA approval

of generic versions of Suboxone Tablet, retained contractors to review and analyze notes of telephone calls to poison control centers regarding accidental child exposure.

80. On or about June 21, 2012, Company A's investor relations director emailed Company A's chief executive officer, INDIVIOR's chief executive officer, and others, referencing "our plans" to withdraw Suboxone Tablet's FDA approval in order to delay FDA approval of generic versions of Suboxone Tablet. Company A's general counsel responded by emailing Company A's chief executive officer, chief financial officer, and investor relations director, and INDIVIOR's chief executive officer and general counsel, and others, stating, "please do not create any emails or other documents suggesting that we would consider" attempting to delay FDA approval of generic versions of Suboxone Tablet in this way, and "any decision we make will be based on consumer safety."

81. On or about August 31, 2012, INDIVIOR's and Company A's contractors provided them with an "interim report" that failed to include any finding that Suboxone Film was safer than tablets with regard to accidental child exposure, or caused any drop in exposures. The interim report stated, "there remains considerable uncertainty in our ability to use root cause analysis for identifying the role of select factors in these unintentional pediatric exposures," and that the data were "insufficient to make any final conclusions regarding the severity of effects associated with specific buprenorphine medications or the child-resistance efficacy of product packaging types." The INDIVIOR manager overseeing the project stated that the interim report was a "worthless, empty shell."

82. On or about September 14, 2012, INDIVIOR executives caused the preparation of a public relations strategy for discontinuing Suboxone Tablet, indicating that INDIVIOR would dispel the "[p]erception of discontinuation as a means for blunting generic/competitive entry"

and convey a "'[w]e must be responsible' sentiment." On or about the same day, INDIVIOR's and Company A's contractors provided INDIVIOR and Company A with a three-page "executive summary" that failed to include any finding that Suboxone Film was safer than tablets with regard to accidental child exposure, or caused any drop in exposures. The summary stated that there were fewer references to Suboxone Film than tablets in the telephone call notes, but the reasons for this could not be determined, and "any results related to the original packaging should be interpreted with considerable caution" because many of the notes did not indicate whether the drug had been in the packaging or left outside the packaging by an adult.

83. On or about September 18, 2012 (about four days later), INDIVIOR and Company A sent a "Notice of Discontinuance" of Suboxone Tablet to the FDA, stating that the reason for the discontinuance was "increasing concerns regarding pediatric exposure to" Suboxone Tablet. INDIVIOR's and Company A's respective chief executive officers approved the notice, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

84. On or about September 25, 2012, INDIVIOR and Company A submitted a petition to the FDA, signed by INDIVIOR's medical director, stating that INDIVIOR discontinued Suboxone Tablet "due to safety concerns" about tablets, and asking the FDA not to approve generic versions of Suboxone Tablet. INDIVIOR's and Company A's respective chief executive officers approved the petition, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

85. The petition referenced a new, five-page version of the executive summary, which INDIVIOR and Company A executives and others had participated in altering, but kept dated September 14, concealing the fact that it was altered from the version they originally cited for

discontinuing Suboxone Tablet. The alterations included deleting the statement that "any results related to the original packaging should be interpreted with considerable caution," and adding conclusions.

86. On or about September 25, 2012, Company A posted on its website a press release stating that Suboxone Tablet was discontinued "due to increasing concerns with pediatric exposure." INDIVIOR's and Company A's respective chief executive officers approved the press release, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

87. INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents used the discontinuation of Suboxone Tablet to materially falsely and fraudulently market Suboxone Film. Between on or about September 18, 2012, and the date of this Indictment, they prepared and caused to be prepared, and shipped and caused to be shipped by mail and private or commercial interstate carrier to their executives and employees and others throughout the United States, letters signed by INDIVIOR's medical director and used to promote Suboxone Film that contained materially false and fraudulent statements and representations, including the following:

a. "Dear Patient . . . The decision to take Suboxone Tablets off the market was a voluntary choice made by [INDIVIOR] as a result of recent information the company received showing higher rates of accidental pediatric exposure (when a child accidentally takes the medicine) linked with the tablet form. If you are currently taking Suboxone Tablets, continue taking your medication and ask your doctor about how to transition to Suboxone Film. . . ."

b. "Dear Healthcare Professional . . . As we continue to work together to improve the health and well-being of opioid-dependent individuals, we would like to personally inform you about an important medication update . . . . The decision to discontinue Suboxone Tablets was based on accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone [Film] compared with the tablet form. . . . We remain committed to supporting you with updated information and resources to ensure you have the tools you need to educate and transition your patients to Suboxone Film. . . . We thank you for your continued support of [INDIVIOR] as we uphold our commitment to patients and the safety of the public."

88. On various dates, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents shipped and caused to be shipped by mail and private or commercial interstate carrier, copies of marketing materials described in paragraph 87 of the Introduction to this Indictment from a contractor in New Jersey to sales representatives throughout the United States.

89. On or about December 4, 2012, the lead researcher from one of INDIVIOR's and Company A's contractors that had reviewed and analyzed notes of telephone calls to poison control centers emailed fellow researchers, stating that by using the research to supposedly justify discontinuing Suboxone Tablet, INDIVIOR and Company A "played us as a pawn and continues to do so. They are smart people, and they are playing a Machiavellian game."

90. It was also a part of the scheme and artifice to defraud that INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents made, and caused to be made, materially false and fraudulent statements and representations to and relating to state Medicaid administrators and others, claiming that

Suboxone Film was safer than tablets with regard to misuse, abuse, diversion, and accidental child exposure. These materially false and fraudulent statements and representations included representations by employees, physicians, and agents, acting on behalf of the defendants, including those on or about the dates set forth below, in or around the specified states, and sent by the physician, employee, or agent identified below:[4]

Par.	Date	State	Sent by	False and Fraudulent Statement and Representation
91	5/17/2011	MA	Physician, at direction of INDIVIOR Gov. Mgrs.	Op-Ed Letter to The Boston Globe, The Boston Herald, and The Patriot Ledger: Suboxone Film was "preventing diversion, recidivism, and the accidental death of inquisitive children," and by declining to provide Medicaid coverage of Suboxone Film, MassHealth officials were "engaging in 21st century biological warfare, no different than giving small pox infected blankets to the Indians"
92	5/30/2011	CA	INDIVIOR Publicist	Quote for article in Alcoholism & Drug Abuse Weekly, News for Policy and Program Decision-makers: "the main value of [Suboxone Film] is that it is less easily diverted because physicians can track the numbered unit-dose packaging, and it is safer because the packaging is child-resistant." INDIVIOR's marketing director emailed INDIVIOR's chief executive officer, president, medical director, and others stating that "[t]here does seem to be some liberty taken with regards to early comments attributed to" INDIVIOR's publicist, but INDIVIOR did not correct or retract the comments
93	6/23/2011	MA	Physician, at direction of INDIVIOR Gov. Mgrs.	Email to MassHealth officials: "there is less opportunity for diversion with" Suboxone Film, "there is less chance that a curious child will ingest the film," and "the inaction by the policy makers of MassHealth can be seen just as Strom Thurmond's filibuster in opposition of the Civil Rights Act of 1957." Physician subsequently emailed INDIVIOR Gov. Mgrs. requesting that INDIVIOR donate $30,000 to his foundation and give him a Harley-Davidson Road King motorcycle as payment
94	10/16/2012	MA	INDIVIOR Med. Mgr.	Email to MassHealth pharmacy director: altered, inaccurate pediatric exposure data for Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets, making it appear as though Suboxone Film had the lowest rate of pediatric exposure in Massachusetts when, in fact, buprenorphine-only tablets did. INDIVIOR Med. Mgr. sent INDIVIOR's medical director email chains showing that she had altered the data, and stating that

[4] These are illustrative examples, not an exhaustive list.

				she sent the altered data to "help us get some movement in Mass" on Medicaid coverage of Suboxone Film. Upon receiving additional data unfavorable to Suboxone Film, INDIVIOR Med. Mgr. declined to provide it to Medicaid personnel, and told INDIVIOR government managers that her rationale for withholding the unfavorable information from Medicaid personnel was, "don't ask, don't tell"
95	4/18/2013	KY	INDIVIOR Gov. Mgr. and INDIVIOR Med.	Email to KY Department for Medicaid Services commissioner and other officials: Compared to Suboxone Film, the tablet form "increases the risk of diversion with adult recipients because it can be crushed and snorted. . . . [S]ometimes leadership requires you to make a decision locally to protect the residents of the State of Kentucky that you serve. You've chosen not to . . . ."
96	Before 12/2013	KY	INDIVIOR Sales Representative	Model form letters shown to physicians to send to KY Department for Medicaid Services contractors: request for pre-authorization for payment of Medicaid claims for Suboxone Film because "Suboxone filmstrips are medically necessary to properly manage the post acute withdrawal process. Filmstrips are necessary in lieu of sublingual tablets because many adverse side effects are found to be prevalent in tablet form. Patient's [sic] present with constant salivation, discomfort, agitation, dissolution unnecessary prolonged. Also, feelings of disorientation, plus a craving for tablets in general, thus hindering the addiction recovery process and increasing probability of relapse. Use of filmstrips has diminished the adverse side effects of tablets. Use of filmstrips eliminates the abuse of tablets, and variation from the prescribed method of ingestion"

D. MARKETING SUBOXONE FILM TO HEALTH CARE PROVIDERS TO BE PRESCRIBED AND DISPENSED IN A CARELESS AND CLINICALLY UNWARRANTED MANNER

97. Beginning on an unknown date, but no later than on or about April 9, 2009, and continuing through the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents did aid, abet, counsel, command, induce, and procure physicians at various locations throughout the United States who they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of

buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner, to switch their prescribing to Suboxone Film.

98. One way in which INDIVIOR encouraged physicians to prescribe Suboxone Film was by including them in INDIVIOR's internet and telephone referral program, called "Here to Help." Patients and prospective patients could use the "Locate a Doctor" tool on the Here to Help website to find physicians prescribing buprenorphine-containing drugs, and could call the Here to Help hotline to receive information about certain physicians and have the call transferred to a physician's office to schedule an appointment. INDIVIOR salespeople told physicians that Here to Help was "like a concierge service."

99. Additionally, INDIVIOR salespeople provided physicians with marketing materials, billing advice, and access to lunch and dinner events through INDIVIOR's "Treatment Advocate" speaker program, including physicians they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner.

100. INDIVIOR executives, employees, and personnel knew from statistical and firsthand reports that certain physicians had prescribed buprenorphine-containing drugs to substantially more patients at a time than allowed by the DATA, at daily doses higher than 24 mgs of buprenorphine, and in a careless and clinically unwarranted manner. No later than in or about April 2009, INDIVIOR managers began receiving statistical reports that identified physicians overprescribing buprenorphine-containing drugs. One manager emailed another, copying INDIVIOR's medical director, stating, "It takes only a short time perusing the

[statistical reports] to realize that we have some serious breaches of [the DATA law's cap on the number of patients a physician may treat] along with very careless and clinically unwarranted prescribing behaviors (% of patients above 24mg)," and certain physicians "need to be removed from the [buprenorphine] practice arena." INDIVIOR managers also received firsthand reports from INDIVIOR salespeople and medical advisors that particular physicians were engaged in "continuous prescribing to patients known to be trafficking in Suboxone/Subutex;" allowing "prescriptions [to be] given when provider not present in office;" "charg[ing] 400 per month" for prescriptions; and suspected of allowing "overt trafficking in provider's parking lot."

101. INDIVIOR executives were aware of the careless, clinically unwarranted prescribing. On or about July 22, 2009, INDIVIOR's chief executive officer wrote to INDIVIOR's vice president for clinical affairs, "I think that the process for reporting rogue physicians is going to be very important." On or about July 14, 2010, INDIVIOR executives met and discussed data indicating that the 564 highest-prescribing physicians in the United States prescribed buprenorphine-containing drugs to an average of more than 200 patients at a time, and the highest prescribers, which INDIVIOR called "Super P8s," accounted for 33% of INDIVIOR's business.

102. INDIVIOR continued to include physicians it knew were issuing careless, clinically unwarranted opioid prescriptions in the Here to Help and Treatment Advocate programs, and otherwise market Suboxone Film to them. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctor A, located in or around Cedar Bluff, Galax, and Willis, Virginia, to switch prescriptions to Suboxone Film where Doctor A exceeded the maximum number of patients allowed at a time,

where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:[5]

Par.	Date(s)	Personnel	Information
103	7/17/2008	INDIVIOR Risk Mgr. to INDIVIOR Med. Advisor	Email: INDIVIOR Risk Mgr. suspected that Doctor A's clinic was one of two possible sources of "1 to 2 controlled buys of Suboxone per week" by law enforcement
104	4/9/2009	INDIVIOR Risk Mgr. and others	Received statistical report: Doctor A prescribed buprenorphine-containing drugs to 805 individuals in February 2009, at daily doses higher than 24 mgs of buprenorphine to 428 of those individuals
105	8/28/2009	INDIVIOR Sales Spvsr. to INDIVIOR Risk Mgr.	Firsthand report: Doctor A intentionally mislabeled prescriptions for buprenorphine-containing drugs as being for pain management, when also prescribed for opioid addiction, to evade detection for violating the DATA patient limit
106	4/30/2010, 6/1/2011, 9/2/2011, 10/6/2011	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas
107	2011	INDIVIOR Sales Rep. to INDIVIOR Sales Spvsr.	Reports: met with Doctor A at least 28 times to encourage Doctor A to prescribe Suboxone Film
108	5/1/2012	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor A, using a list of enrolled prescribers in the patient's geographic area
109	5/10/2012	INDIVIOR Sales Rep. to INDIVIOR Med. Advisor	Email: successfully convinced Doctor A to switch to prescribing Suboxone Film, as "Basically I lived with [Doctor A] last fall, seeing her once or twice a week, every week, even Saturdays; and eventually it paid off and her share of tablet vs film completely flip flopped"
110	4/12/2013, 4/26/2013	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas
111	9/10/2013	INDIVIOR Sales Rep. to INDIVIOR Risk Mgr.	Firsthand report: Doctor A is "[m]assively over cap [the maximum patient limit allowed under the DATA] . . . she also overdoses. . . . This has been an ongoing problem since I started that only continues to get worse"
112	12/13/2013, 11/3/2014, 3/10/2015, 3/13/2015, 3/18/2015,	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor A, using lists of enrolled prescribers in the patients' geographic areas

[5] These are illustrative examples, not an exhaustive list.

	4/27/2015, 5/26/2015, 5/26/2015, 6/18/2015, 7/8/2015		

113. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctors B and C, located in or around Johnson City, Tennessee, to switch prescriptions to Suboxone Film where Doctors B and C exceeded the maximum number of patients allowed at a time, where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:

Par.	Date(s)	Personnel	Information
114	4/9/2009	INDIVIOR Risk Mgr. and others	Received statistical report: in March 2009, Doctor B prescribed buprenorphine-containing drugs to 650 individuals, at daily doses higher than 24 mgs of buprenorphine to 618 of those individuals, and Doctor C prescribed buprenorphine-containing drugs to 635 individuals, at daily doses higher than 24 mgs of buprenorphine to 272 of those individuals
115	4/9/2009	INDIVIOR Employee, INDIVIOR Med. Advisor, and INDIVIOR Sales Spvsr.	Email re statistical report: "Notice your favorite, [Doctor B], is still at the top. I think now you can feel much more certain that he is likely a big source of diversion – 95% (618) of his patients are over 24mg. Wow!" Email further discussing report: "It appears that the 'high' doses may be the contributing factor to the diversion that continues to be reported in the Tri-Cities area of SE KY, NE TN, and SW VA"
116	5/28/2009	INDIVIOR Risk Mgr. to INDIVIOR Exec.	Email: "I am concerned about the Tri-Cities area in northeast Tennessee (also includes southeast KY and southwest VA). Physicians are prescribing for too many patients and the dosing is very high in some circumstances. 14 treating over 200 patients – range 200 to 800. 8 of 14 are prescribing doses >24 mg for at least 50% of their patients"
117	7/6/2009, 12/14/2009, 12/18/2009	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor C, using lists of enrolled prescribers in the patients' geographic areas
118	2/3/2010	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor B, using a list of enrolled prescribers in the patient's geographic area

119	2/5/2010	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area
120	4/8/2010	INDIVIOR Sales Sprvsr. to INDIVIOR National Sales Sprvsr.	Email: Doctor B is "well over the allowed patient cap," and Doctor C's office "will prescribe to as many patients as they can fit in [while physicians are] in about 2-3 hours each week. In that time they quickly see the patient & provide a script"
121	6/2/2010	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area
122	11/20/2010	INDIVIOR Exec. to INDIVIOR Salespeople	Award: INDIVIOR sales rep. marketing Suboxone Film to Doctors B and C named Suboxone Film Marketing Blitz "Contest Winner" and credited with "incredible performance . . . 13 times the initial Contest patient threshold"
123	2010	INDIVIOR Exec. to INDIVIOR Salespeople	Award: INDIVIOR sales rep. marketing Suboxone Film to Doctors B and C recognized as INDIVIOR's sales rep. of the year
124	2010-2011	INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr.	Reports: met with Doctors B and C at least 75 times to encourage them to prescribe Suboxone Film
125	1/23/2012	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area
126	4/22/2013	INDIVIOR Sales Rep. and INDIVIOR Sales Sprvsr. to INDIVIOR Mgr.	Conversation: "It's a liability almost that we're even walking into these offices, these two main clinic offices [of Doctor C], because of how criminal it is. Like they have a Vegas-style cash machine sitting behind the office where they're taking stacks of hundreds and shoving it in there while we're trying to like, detail the nurse. It's like the mob. It's awful"
127	8/9/2013	"Here to Help" telephone operator	Here to Help operator referred an opioid-addiction/dependence patient to Doctor C, using a list of enrolled prescribers in the patient's geographic area

128. On or about the stated dates, the identified INDIVIOR executives, employees, and agents communicated the information described below relating to aiding, abetting, counseling, commanding, inducing, and procuring Doctor D, located in or around Danville, Kentucky, to switch prescriptions to Suboxone Film where Doctor D exceeded the maximum number of patients allowed at a time, where daily doses exceeded the maximum indicated for additional clinical advantage, and where prescriptions were issued in a careless and clinically unwarranted manner:

Par.	Date(s)	Personnel	Information
129	6/25/2008	INDIVIOR Sales Sprvsr. to INDIVIOR Sales Rep.	Coaching form: "Continue to Partner with [Doctor D's clinic] and their growing . . . organization. While it can appear the program is on auto-pilot, they still have much to learn, and we can help"
130	7/11/2008	INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr.	Report: "The 2nd [office of Doctor D's clinic] opened in Barboursville, the third one is scheduled to open in August and that will be in Frankfurt. The plan is to have 10 physicians in each clinic. Expanding trx in the South, one clinic at a time!"
131	12/17/2008	INDIVIOR Med. Advsr. to INDIVIOR Risk Mgr. and INDIVIOR Sales Sprvsr.	Email: Doctor D "is in difficulties with his organization of 30 MDs related to prescribing of Suboxone. This stems perhaps from a couple of problem patients and led to a state board investigation. Most of their patients are on 24 mg daily. . . . Is this group in Kentucky an area of concern for us? Is there any follow-up needed?"
132	7/23/2009, 8/13/2009, 8/31/2009	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas
133	9/23/2009	Doctor D to INDIVIOR Gov. Mgr. and INDIVIOR Sales Rep.	Email: "We are even more excited about the opportunities we have to facilitate each others' [sic] success. . . . We will keep our noses to the grindstone getting our program of care 'refined' and ask that you continue to keep your brain grinding on how to best 'use' us everywhere and any way it makes sense. We will keep [INDIVIOR] updated as we collaborate with Medicaid, private payors, the VA system, and anything/anyone else we come across. We are pursuing multiple grants as of yesterday evening for the call centerdatabase [sic]/website plan and indigent care for opiate addicts (those with no pay source), but if there is any way [INDIVIOR] can get involved financially, there will be great business benefit for [INDIVIOR] in the end (more patients being prescribed SBX) and amazing PR for each state you support"
134	9/23/2009	INDIVIOR Sales Sprvsr. to INDIVIOR Gov. Mgr.	Email: "We have had a difficult time giving [Doctor D] what he wanted, because most of his requests are out of pharma guidelines. . . . I can see you were able to provide him with opportunities and information that he sees as very valuable to his treatment center plans and goals. Thank you for helping [ensure Doctor D's clinic] sees the Integrated Value [INDIVIOR] has to offer"
135	1/4/2010, 5/13/2010, 5/17/2010, 9/7/2010, 9/30/2010, 10/19/2010, 10/26/2010, 11/10/2010	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas

136	12/8/2010	Doctor D to INDIVIOR Gov. Mgrs., INDIVIOR Sales Rep., and others	Report: in one month, Doctor D's clinic had prescribed buprenorphine-containing drugs to 1,659 individuals, at daily doses higher than 24 mgs of buprenorphine to 39% of them, and at daily doses of at least 24 mgs of buprenorphine to 76% of them. INDIVIOR's Public Sector Dir. forwarded the report to others at INDIVIOR, stating, "[w]ith over 76% of the patients at 24 mg and above, we have some serious work today in educating his organization and the physicians about dosing and overall quality care. The reverse should likely be the case"
137	12/23/2010, 1/5/2011, 1/10/2011, 1/28/2011, 3/25/2011, 4/21/2011, 4/22/2011, 5/5/2011, 5/11/2011, 5/16/2011, 5/17/2011, 5/25/2011, 6/8/2011, 6/27/2011, 8/12/2011, 8/15/2011, 8/19/2011, 9/15/2011, 10/3/2011, 10/19/2011, 11/4/2011, 11/30/2011	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas
138	2011	INDIVIOR Exec. to INDIVIOR Salespeople	Award: INDIVIOR sales rep. marketing Suboxone Film to Doctor D's clinic recognized as INDIVIOR's sales rep. of the year
139	2/2/2012	INDIVIOR Sales Rep. to INDIVIOR Sales Sprvsr.	Email: INDIVIOR to sponsor Doctor D's clinic's annual meeting, including breakfast and lunch for 46 people
140	2/13/2012, 2/16/2012, 3/7/2012, 4/9/2012, 4/18/2012, 5/2/2012, 5/16/2012	"Here to Help" telephone operators	Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas

141	6/4/2012	Kentucky Board of Medical Licensure	Indefinite restriction of Doctor D's authorization to prescribe buprenorphine-containing drugs for use in opioid addiction/dependence treatment
142	6/25/2012 through 12/2/2016	"Here to Help" telephone operators	About 140 instances in which Here to Help operators referred opioid-addiction/dependence patients to Doctor D, using lists of enrolled prescribers in the patients' geographic areas
143	11/5/2015 through 3/31/2017	United States District Court for the Eastern District of Kentucky	Doctor D indicted on 11/5/2015 for health care fraud related to urine testing; found guilty of 17 counts on 3/31/2017

SUBOXONE TABLET PRICE INCREASES TO SUPPORT SCHEME

144. Between in or about 2010 and the date of this Indictment, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and their executives, employees, and agents also increased the price of Suboxone Tablet to cause patients to switch to Suboxone Film. In or about October 2011, an INDIVIOR manager told colleagues, "I could not support a tablet [price] increase again before next October. That would be essentially another 37% over 24 months. . . . If we are considering the patient in all of this, then we need to understand that 40% will have to remain on the tablet due to supply constraints. . . . We also need to consider the public health backlash and that of physicians." In or about July 2012, INDIVIOR increased the price of Suboxone Tablet by 15%, stating the "Rationale of Price Increase" as "accelerate conversion to Film."

REVENUE AND PROFIT

145. In or about the specified years, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) and Company A received approximately the following revenues from sales of Suboxone Film:

Year	Revenue
2010	$83,328,721
2011	$400,615,412
2012	$666,695,781

2013	$887,469,559
2014	$843,047,500

In or about the same years, Medicare and Medicaid payments for Suboxone Film were approximately as follows:

Year	Medicare	Medicaid
2010	$2,134,000	$7,136,000
2011	$26,188,000	$108,079,000
2012	$70,329,000	$211,294,000
2013	$132,984,000	$326,666,000
2014	$147,704,000	$386,685,000

146. In or about September 2012, Company A stated that it would give "special recognition awards" of thousands of shares of Company A stock to about ten INDIVIOR executives and managers for the commercial success of Suboxone Film, saying it had "created a long-term sustainable business model for" INDIVIOR.

147. On or about August 5, 2013, INDIVIOR's chief executive officer emailed Company A's chief executive officer and others, stating that Suboxone Film's share of the market had grown to 69.1%, which was "almost enough to make you wonder when we will break through the 70% share barrier?" Company A's chief executive officer replied-all, "I agree, our US team has done a fantastic job of defending our film share thus far."

148. On or about November 17, 2013, INDIVIOR's chief executive officer stated to an INDIVIOR manager that in switching physicians, pharmacists, health care benefit programs, and others to Suboxone Film, INDIVIOR had achieved "the best format conversion ever in the history of the industry."

COUNT ONE
Conspiracy to Commit Mail, Wire, and Health Care Fraud

The Grand Jury charges that:

1. The Introduction to this Indictment and the factual allegations of Counts Two through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury knowingly conspired to commit the following offenses:

a. Mail fraud, in violation of Title 18, United States Code, Section 1341, that is, having devised and intending to devise the scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises described in the Introduction to this Indictment, and for the purpose of executing such scheme and artifice and attempting to do so, did knowingly cause to be delivered by the Postal Service and any private or commercial interstate carrier certain matters and things according to the directions thereon;

b. Wire fraud, in violation of Title 18, United States Code, Section 1343, that is, having devised and intending to devise the scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises described in the Introduction to this Indictment, and for the purpose of executing such scheme and artifice and attempting to do so, transmitted and caused to be transmitted by means of wire communication in interstate commerce writings, signals, and sounds;

c. Health care fraud, in violation of Title 18, United States Code, Section 1347, that is, knowingly and willfully executed and attempted to execute the scheme and artifice to defraud and to obtain by means of materially false and fraudulent pretenses, representations, and promises money and property owned by and under the custody and control of Medicare, Medicaid, private insurance providers, and other health care benefit programs in connection with the delivery of and payment for health care benefits, items, and services, described in the Introduction of this Indictment.

3. In furtherance of the conspiracy, and to effect its object, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury committed the overt acts described in the Introduction to this Indictment, and Counts Two through Twenty-eight of this Indictment.

4. All in violation of Title 18, United States Code, Section 1349.

COUNT TWO
Health Care Fraud

The Grand Jury charges that:

1. The Introduction to this Indictment and the factual allegations of Counts One and Three through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, as principals and aiders and abettors, knowingly and willfully executed and attempted to execute a scheme and artifice to (1) defraud health care benefit programs as defined in Title 18, United States Code, Section 24(b), including Medicaid, Medicare, other public health care programs, private insurance providers, and other health care benefit programs, and (2) obtain by means of

materially false and fraudulent pretenses, representations, and promises, money and property owned by and under the custody and control of said health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services.

3. It was the object of the scheme and artifice to fraudulently induce physicians to write prescriptions for Suboxone Film, pharmacists to fill prescriptions for Suboxone Film, and health care benefit programs to provide coverage of prescriptions for Suboxone Film, and to cause:

a. Patients to obtain Suboxone Film from pharmacies and others;

b. Patients, pharmacies, and others to submit claims for Suboxone Film to health care benefit programs;

c. Health care benefit programs to pay claims for Suboxone Film;

d. Pharmacies and others to make payments to wholesalers, distributors, and others for Suboxone Film; and

e. Wholesalers, distributors, and others to make payments to INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) for sales of Suboxone Film made as a result of the scheme and artifice to defraud.

4. In furtherance of the scheme and artifice, and to effect its object, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, for the purpose of causing health care providers and others to prescribe and dispense Suboxone Film, and to recommend the prescribing and dispensing of Suboxone Film, did, and aided, abetted, counseled, commanded, induced, and procured others to, make materially false and fraudulent statements and representations, including the following:

a. Representing to physicians, pharmacists, and other health care providers that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, and has other unsubstantiated effects such as weeding out drug seekers, making patients feel less like addicts, protecting physicians from being criminally prosecuted, and protecting office-based treatment of opioid addiction/dependence from being banned;

b. Producing and disseminating printed marketing materials representing that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, containing misleading text, graphics, and charts;

c. Representing to government officials, employees, and agents administering various state Medicaid programs, and others, that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, to cause such government officials, employees, and agents, and others to expand and maintain Medicaid coverage of Suboxone Film at substantial cost to the government and substantial profit to the defendants; and

d. Providing patient referrals, presentations, marketing materials, access to lunch and dinner events, and other benefits to physicians they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than the maximum dose of any demonstrated additional clinical advantage (*i.e.*, 24 mgs of buprenorphine), and in a careless and clinically unwarranted manner.

5. All in violation of Title 18, United States Code, Sections 2 and 1347.

COUNTS THREE THROUGH SIX
Mail Fraud

The Grand Jury charges that:

1. The Introduction and the factual allegations of Counts One through Two and Seven through Twenty-eight are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, with the intent to defraud, devised and willfully participated in, with knowledge of its fraudulent nature, the scheme and artifice to defraud and obtain money and property by materially false and fraudulent pretenses, representations, and promises described in the Introduction and in the factual allegations of Counts One through Two and Seven through Twenty-eight of this Indictment.

3. On or about the date specified as to each count below, in the Western District of Virginia, for the purpose of executing and attempting to execute such scheme and artifice to defraud, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury caused to be delivered by mail and private or commercial interstate carrier according to the direction thereon, the named matter and thing, namely, marketing visual aids containing materially false and fraudulent representations that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child exposure than other, similar drugs, including misleading text, graphics, and charts, to an INDIVIOR sales representative in Roanoke, Virginia, who promoted Suboxone Film to physicians, pharmacists, and others in locations including Blacksburg, Cedar Bluff, Charlottesville, Christiansburg, Danville, Galax, Lynchburg, Roanoke, Salem, Staunton, Willis, and Wytheville, Virginia:

COUNT	DATE
THREE	February 6, 2012
FOUR	January 4, 2013
FIVE	March 21, 2013
SIX	August 19, 2013

4. All in violation of Title 18, United States Code, Sections 2 and 1341.

COUNTS SEVEN THROUGH TWENTY-EIGHT
Wire Fraud

The Grand Jury charges that:

1. The Introduction and the factual allegations of Counts One through Six are realleged and incorporated as if fully set forth herein.

2. Between in or about 2006 and the date of this Indictment, in the Western District of Virginia and elsewhere, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, with the intent to defraud, devised and willfully participated in, with knowledge of its fraudulent nature, the scheme and artifice to defraud and obtain money and property by materially false and fraudulent pretenses, representations, and promises described in the Introduction and the factual allegations of Counts One through Six of this Indictment.

3. On or about the date specified as to each count below, in the Western District of Virginia and elsewhere, for the purpose of executing and attempting to execute such scheme and artifice to defraud, INDIVIOR PLC, INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.), and others known and unknown to the Grand Jury, caused to be transmitted by wire communication or radio communication in interstate and foreign commerce, writings, signs, signals, pictures, and sounds, namely, reports of clinical liaisons falsely and fraudulently representing to physicians, pharmacists, and other health care providers that Suboxone Film is safer and less susceptible to misuse, abuse, diversion, and accidental child

exposure than other, similar drugs, transmitted from Florida and New Jersey to locations in the Western District of Virginia, and referrals of prospective patients to Doctor A, transmitted from Pennsylvania to locations in the Western District of Virginia, as described below:

COUNT	DATE	ITEM
SEVEN	April 30, 2010	Referral to Doctor A
EIGHT	October 9, 2010	Activity Report with Model Safety Claims
NINE	October 24, 2010	Activity Report with Model Safety Claims
TEN	November 29, 2010	Activity Report with Model Safety Claims
ELEVEN	June 1, 2011	Referral to Doctor A
TWELVE	July 8, 2011	Activity Report with Model Safety Claims
THIRTEEN	September 2, 2011	Referral to Doctor A
FOURTEEN	October 6, 2011	Referral to Doctor A (1 of 2 on this date)
FIFTEEN	October 6, 2011	Referral to Doctor A (2 of 2 on this date)
SIXTEEN	May 1, 2012	Referral to Doctor A
SEVENTEEN	April 12, 2013	Referral to Doctor A
EIGHTEEN	April 26, 2013	Referral to Doctor A
NINETEEN	December 13, 2013	Referral to Doctor A
TWENTY	November 3, 2014	Referral to Doctor A
TWENTY-ONE	March 10, 2015	Referral to Doctor A
TWENTY-TWO	March 13, 2015	Referral to Doctor A
TWENTY-THREE	March 18, 2015	Referral to Doctor A
TWENTY-FOUR	April 27, 2015	Referral to Doctor A
TWENTY-FIVE	May 26, 2015	Referral to Doctor A (1 of 2 on this date)
TWENTY-SIX	May 26, 2015	Referral to Doctor A (2 of 2 on this date)
TWENTY-SEVEN	June 18, 2015	Referral to Doctor A
TWENTY-EIGHT	July 8, 2015	Referral to Doctor A

4. All in violation of Title 18, United States Code, Sections 2 and 1343.

NOTICE OF FORFEITURE

1. The Introduction and the factual allegations of Counts One through Twenty-Eight of this Indictment are realleged and made part of this Notice.

2. Upon conviction of one or more of the felony offenses alleged in this Indictment, INDIVIOR PLC and INDIVIOR INC. (also known as Reckitt Benckiser Pharmaceuticals Inc.) shall forfeit to the United States:

a. pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes, or is derived from proceeds traceable to a violation of any offense constituting "specified unlawful activity" (as defined in section 1956(c)(7)), or a conspiracy to commit such offense; and

b. pursuant to 18 U.S.C. § 982(a)(7), property, real or personal, that constitutes, or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

3. The property to be forfeited to the United States includes, but is not limited to, the following:

a. **Monetary Judgment:** Not less than $3,000,000,000 (three billion dollars) in United States currency and all interest and proceeds traceable thereto, in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

b. **Business Entities (including all assets, inventory, and property related thereto):** Indivior Finance (2014) LLC; Indivior Finance SARL; Indivior Global Holdings Ltd (a/k/a RBP Global Holdings Limited); Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.); Indivior PLC; Indivior Solutions Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Solutions Inc.); and Indivior US Holdings Inc. (f/k/a RBP US Holdings Inc.).

c. **Bank Accounts, all funds received and on deposit as set forth below:**

	Bank	Account Name	Account #
(1)	JP Morgan Chase	Indivior Inc.	[redacted]299
(2)	JP Morgan Chase	Indivior Inc.	[redacted]419
(3)	JP Morgan Chase	Indivior Inc.	[redacted]420

(4)	JP Morgan Chase	Indivior Solutions Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Solutions Inc.)	[redacted]148
(5)	Institutional Cash Distributors (ICD), LLC	Indivior Inc./Indivior plc	

4. If any of the above-described forfeitable property, as a result of any act or omission of the defendant, cannot be located upon the exercise of due diligence; has been transferred or sold to or deposited with a third person; has been placed beyond the jurisdiction of the Court; has been substantially diminished in value; or has been commingled with other property which cannot be subdivided without difficulty; it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above described forfeitable property pursuant to 21 U.S.C. § 853(p), including the assets described above, and including but not limited to the following assets:

a. **Trademarks:**

	Serial No., Registration No.
(1)	86779039
(2)	86779033
(3)	86779029
(4)	86779026
(5)	79151424, 4718643

b. **Patents:**

	Patent Number	**Patent Title**
(1)	8,475,832	Sublingual and buccal film compositions
(2)	8,497,280	Medicinal compositions comprising buprenorphine and nalmefene

(3)	8,697,718	Pack of medicinal tablets
(4)	8,912,211	Medicinal compositions comprising buprenorphine and naltrexone
(5)	8,921,387	Injectable flowable composition comprising buprenorphine
(6)	8,975,270	Injectable flowable composition comprising buprenorphine
(7)	9,101,625	Buprenorphine-wafer for drug substitution therapy
(8)	9,180,197	Sustained delivery formulations of risperidone compounds
(9)	9,186,413	Sustained delivery formulations of risperidone compounds
(10)	9,272,044	Injectable flowable composition buprenorphine
(11)	9,370,512	Buprenorphine-wafer for drug substitution therapy

c. **Accounts Receivable, all amounts due from the following entities:**

(1)	Amerisource Bergen
(2)	ANDA
(3)	Besse Medical
(4)	Burlington Drug
(5)	Capital Wholesale
(6)	Cardinal Health
(7)	Dakota Drug Inc
(8)	Dixon Shane LLC
(9)	DMS Pharmaceutical Group
(10)	Harvard Drug Group
(11)	HD Smith Wholesale
(12)	Integrated Commercialization Solutions
(13)	JM Smith
(14)	Louisiana Wholesale Drug Company

(15)	Luis Garraton
(16)	McKesson
(17)	Miami-Luken Inc.
(18)	Morris Dickson
(19)	MWI Vet Supply
(20)	NC Mutual Wholesale
(21)	Prescription Supply Company
(22)	Quality King Distributors
(23)	R & S Sales
(24)	Rochester Drug Cooperative
(25)	Smith Drug Company
(26)	Valley Wholesale Drug Company
(27)	Value Drug Company

A TRUE BILL, this 14 day of August, 2019.

/s/ Grand Jury Foreperson

Randy Ramsey
for DANIEL P. BUBAR
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

GUSTAV W. EYLER
Director
Consumer Protection Branch
Department of Justice

EXHIBIT 3

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20CR00024
v.	)	
	)	**Violations:**
SHAUN THAXTER	)	**21 U.S.C. §§ 331(a), 352(a), 333(a)(1)**
	)	

INFORMATION

The United States charges that:

DEFENDANT

1. At all times relevant to this Information, the defendant, SHAUN THAXTER, was a resident of Richmond, Virginia.

2. At all times relevant to this Information through on or about December 23, 2014, THAXTER was the highest-ranking executive of Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), a Delaware corporation with offices in Richmond, Virginia, that conducted business in the Western District of Virginia and elsewhere. RBP was a subsidiary of Company A. As the highest-ranking executive of RBP, THAXTER reported to the Chief Executive Officer of Company A.

3. On or about December 23, 2014, RBP was demerged from Company A. Following the demerger, RBP was renamed Indivior Inc. and became a subsidiary of Indivior PLC, a United Kingdom company with offices in Slough, England, and Richmond, Virginia, that conducted business in the Western District of Virginia and elsewhere. After on or about December 23, 2014, THAXTER was the Chief Executive Officer of Indivior PLC.

4. Indivior Solutions, Inc., previously known as Reckitt Benckiser Pharmaceutical Solutions, Inc., is a wholly owned subsidiary of Indivior Inc. Indivior Solutions, Inc. is a Delaware corporation headquartered in Richmond, Virginia. At all times relevant to this Information,

THAXTER had responsibility for and authority over Indivior Solutions, Inc. This Information refers to RBP, Indivior Inc. and Indivior Solutions, Inc. collectively as "Indivior."

5. At all times relevant to this Information, Indivior was engaged in the pharmaceutical business throughout the United States, including in the Western District of Virginia. Indivior's business included marketing, promotion, field sales, managed-care sales, and field-medical functions for drugs containing buprenorphine, an opioid, under brand names including Suboxone and Subutex.

LEGAL BACKGROUND

6. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans is a drug. 21 U.S.C. § 321(g).

7. The FDCA prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug or the causing thereof. 21 U.S.C. § 331(a). Under 21 U.S.C. § 333(a)(1) and applicable case law, a responsible executive with authority to either prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce may be liable for a misdemeanor violation of 331(a).

8. The FDCA provides that a drug is misbranded if, among other things, its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a). "Labeling" includes "brochures, booklets . . . letters . . . exhibits [and] literature . . . descriptive of a drug" whether or not it physically accompanies the drug when distributed. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2). Considering whether labeling is misleading requires assessing "the extent to which

the labeling . . . fails to reveal facts" that are "material" in light of "representations made or suggested by statement, word, design, device, or any combination thereof." 21 U.S.C. § 321(n).

SUBOXONE PRODUCTS

9. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continue to take opioids under medical supervision to avoid or reduce withdrawal symptoms while they seek to recover. The only opioid medication approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take at home) was buprenorphine, an opioid partial agonist and Schedule III controlled substance under the Controlled Substances Act.

10. On or about October 8, 2002, Indivior received approval from the Food and Drug Administration ("FDA") for the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet ("Suboxone Tablet") and Subutex Sublingual Tablet ("Subutex Tablet"). Indivior had previously obtained orphan-drug designation for buprenorphine for the "treatment of opioid addiction in opioid users." Among other things, this designation meant that Suboxone and Subutex were potentially eligible for 7-years of orphan-drug exclusivity upon approval (which would prohibit FDA from approving any competing application for buprenorphine for the same indication for 7 years). After approving these drugs, FDA determined that they were eligible and granted them orphan-drug exclusivity.

11. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but it could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps.

12. Subutex Tablet was similar to Suboxone Tablet, but it did not include naloxone. It was intended for induction and certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps.

13. In 2007, as Suboxone Tablet and Subutex Tablet neared the end of their period of exclusivity, Indivior began developing a new buprenorphine-containing drug for use in opioid addiction/dependence treatment: Suboxone Sublingual Film ("Suboxone Film").

14. Like Suboxone Tablet, Suboxone Film was a combination of buprenorphine and naloxone, but because aspects of the film formulation were patented, it arguably had patent protection. Suboxone Film differed from Suboxone Tablet in that (among other things) it has a thin form; sticks to the tongue/mouth; dissolves more rapidly; has potentially greater relative bioavailability at certain doses (as stated in the FDA-approved label); is formulated to taste better; and is packaged in individually wrapped, child-resistant foil pouches.

15. In August 2010, Indivior received approval from the FDA to market Suboxone Film for use in the treatment of opioid addiction/dependence.

16. At times relevant to this Information, Indivior marketed Suboxone Film to physicians and healthcare programs throughout the United States, including the Western District of Virginia.

PEDIATRIC EXPOSURE RISK

17. Suboxone Tablet, Subutex Tablet, and Suboxone Film, like many other drugs, carry a risk to children who take them by accident, sometimes called "unintended pediatric exposure." This risk of unintended pediatric exposure is identified in the Important Safety Information in

Suboxone's FDA-approved labeling, on its package, and in a Medication Guide and Physician Brochure with instructions on safe storage of the drug.

18. Indivior executives, including THAXTER, received data from poison control centers on unintended pediatric exposure for all buprenorphine drugs. During 2012 and thereafter, Indivior contracted with the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS") to analyze the data for rates and trends.

PROMOTION AND DISTRIBUTION OF SUBOXONE FILM TO MASSHEALTH WITH MISLEADING LABELING

19. At all times relevant to this Information, sales of Suboxone Tablet, Subutex Tablet, and Suboxone Film generated substantially all of Indivior's revenue. After Indivior received FDA approval in August 2010 to market Suboxone Film, the company actively promoted only Suboxone Film. THAXTER and other executives structured the bonuses and incentives for sales employees to reward only Suboxone Film sales. Indivior used the RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film.

20. Before in or around December 2012, Suboxone Film was not a preferred drug on the Massachusetts Medicaid program ("MassHealth") formulary and had restrictions on approval for reimbursement. MassHealth was the largest Medicaid program in the country by volume of addiction-treatment-drug business. Thus, Indivior, and THAXTER, placed high importance on persuading MassHealth to expand coverage of Suboxone Film.

21. On or about January 11, 2011, THAXTER received an email from an Indivior Senior Manager, indicating that MassHealth was considering expanding coverage of a different, non-opioid drug for use in the treatment of opioid addiction/dependence. In response, THAXTER emailed Indivior's top State Government Affairs employee, copying its Vice President for Sales and Marketing, asking for a "strategy to counter" that drug. Indivior's top State Government

Affairs employee replied by email to THAXTER, laying out a multi-pronged plan that included using "a Strategic Communications approach to bring forward . . . the poison control data that demonstrates the number of unintended exposures and how [Suboxone Film] holds promise to address" the risk of unintended pediatric exposure.

22. On or about May 16, 2012, after THAXTER failed to secure a meeting with a MassHealth official, Indivior's Managed Care Director wrote to THAXTER, "Shaun: Thanks for the efforts . . . . We know how important MassHealth is and it is #1 ranked Medicaid [for us] by volume in the U.S. . . . My suggestions (in confidence not to be shared): 1) We build our pediatric poison campaign with the largest poison control centers in Mass. and we demonstrate the public health impact" to MassHealth.

23. On or about October 2, 2012, THAXTER and other executives received an email from Indivior's Medical Affairs Manager. In the email, the Medical Affairs Manager stated that a MassHealth official had reached out "requesting a meeting with me in his offices." The Medical Affairs Manager noted, "I am very excited at this opportunity to share the pediatric data," but asked to attend the meeting alone because "the situation is very delicate." "You can rest assured," the Medical Affairs Manager wrote, "that we will have a successful meeting and things will change in Massachusetts." THAXTER responded: "Sorry I missed the discussion. My contribution is that I would like [Indivior's Global Medical Director and Vice President for Clinical Affairs] to attend the meeting as well. I agree that we commercial people should not attend this meeting."

24. On or about October 9, 2012, Indivior's Medical Affairs Manager met with the MassHealth official and provided a RADARS analysis of unintended pediatric exposure data from poison control centers nationwide. Following the meeting, the Medical Affairs Manager emailed a report of the meeting to THAXTER and others, stating that the MassHealth official was "very

responsive to the pediatric data," and adding, "[b]ecause RADARS can analyze exposure data to the 3-digit zip code in the US, my next step is that I have asked [RADARS] to do an immediate analysis of the rates of unintended pediatric exposure to buprenorphine tablets in Massachusetts as the utilization of tablets is high there and I expect that the rates of exposure follow suit. I am going to follow up with a telephone meeting with [the MassHealth official] to share this information." The Medical Affairs Manager then asked RADARS for an analysis of unintended pediatric exposure data for Massachusetts only, *i.e.*, a Massachusetts-specific analysis, to provide to the MassHealth official.

25. The next day, on or about October 10, 2012, RADARS provided the Medical Affairs Manager with the Massachusetts-specific analysis. It showed the rates of unintended pediatric exposure in Massachusetts for three categories of drugs: Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets such as Subutex Tablet (sometimes called "mono tablets"). The analysis showed that, in Massachusetts, there were 3.3 exposures per 10,000 units for Suboxone Tablets, 2.7 exposures per 10,000 units for Suboxone Film, and 1.8 exposures per 10,000 units for buprenorphine-only tablets such as Subutex Tablet. These data showed that buprenorphine-only tablets like Subutex Tablet—which are packaged in bottles with child-resistant caps, in the same manner as Suboxone Tablet and many other drugs—had the lowest rate of unintended pediatric exposure among the three categories in Massachusetts.

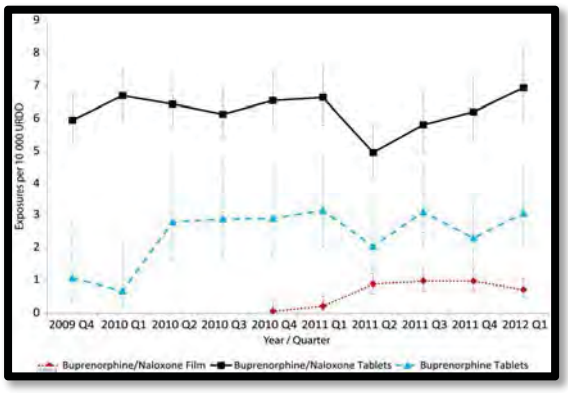
26. Upon receiving the analysis, the Medical Affairs Manager asked RADARS (copying Indivior's Global Medical Director) if she could "just add the mono and combination tablets to see the difference from film."

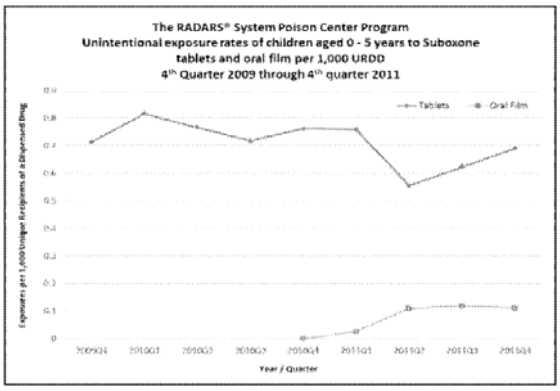
27. On or about October 16, 2012, the Medical Affairs Manager sent the MassHealth official an email containing false and misleading statements. The email contained a calculation of

the unintended pediatric exposure data for Massachusetts that added the two tablet rates together when, in fact, adding the two tablet rates together would not provide an accurate calculation. Further, the Medical Affairs Manager indicated to the MassHealth official that she had received the calculations from RADARS when, in fact, she had not received them from RADARS, but had done the calculations herself. The Medical Affairs Manager stated to the MassHealth official, and her calculations appeared to show, that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts when, in fact, buprenorphine-only tablets like Subutex Tablet had the lowest rate in Massachusetts, according to the RADARS data. The Medical Affairs Manager also forwarded her email to Indivior's Global Medical Director, stating that she sent it to the MassHealth official to "help us get some movement in Mass."

28. On or about November 19, 2012, responding to a follow-up question about her false and misleading email referenced in the preceding paragraph, the Medical Affairs Manager sent the MassHealth official an email containing a chart with information from an Indivior promotional brochure (see image on right below) that referenced pediatric exposure data comparing the two products that contained both buprenorphine and naloxone, indicating that Suboxone Film had a substantially lower rate of pediatric exposure than Suboxone Tablets. The chart did not include a third line of data known to the Medical Affairs Manager that showed Subutex Tablets (which contain only buprenorphine, and not naloxone) with a lower rate of pediatric exposure than Suboxone Tablets, and with less of a difference in the rate of pediatric exposure than Suboxone Film (see image on left below). Shared in light of the Medical Affairs Manager's prior false and misleading email about unintended pediatric exposure rates in Massachusetts, the chart without the third line of data failed to reveal facts material to MassHealth prior to its updated formulary decision. By not including the data related to Subutex Tablets, the Medical Affairs Manager

reinforced her false and misleading claim that Massachusetts-specific data showed Suboxone Film as having the lowest rate of unintended pediatric exposure in the state.





29. Subsequently, the Medical Affairs Manager received additional unintended-pediatric-exposure data showing that Suboxone Film did not have the lowest rate of unintended pediatric exposure in Massachusetts, but she did not provide the data to MassHealth. The Medical Affairs Manager later told other Indivior employees, but not including THAXTER, that her rationale for withholding the additional data from MassHealth was, "don't ask, don't tell."

30. In or about December 2012, MassHealth issued a press release announcing that it would "provide access to the unit-dosed film formulation to those members prescribed Suboxone who live in households with children less than six years of age," citing to Indivior's nationwide pediatric exposure-rate data.

31. Indivior failed to correct the false and misleading statements made to MassHealth about unintended pediatric exposure in Massachusetts until December 2015, approximately two years after the government's investigation had begun. After learning of the statements, THAXTER approved sending a correction letter to MassHealth.

32. THAXTER, as a responsible Indivior executive, failed to prevent and promptly correct the distribution of the false and misleading unintended pediatric exposure data and marketing claims to MassHealth.

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COUNT ONE
Introduction of Misbranded Drugs in Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), 352(a)

33. Therefore on dates set forth in this Information, in the Western District of Virginia and elsewhere, the defendant,

SHAUN THAXTER,

a responsible Indivior executive, caused the introduction and delivery for introduction into interstate commerce of Suboxone Film, a drug that was misbranded in that the drug's labeling was false and misleading. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(a).

NOTICE OF FORFEITURE

1. Upon conviction of the offense alleged in this Information, SHAUN THAXTER shall forfeit to the United States pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c), any quantities of drugs which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331.

2. If any of the property described above as being subject to forfeiture, which valued at approximately $500,000, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;
b. has been transferred or sold to, or deposited with a third person;
c. has been placed beyond the jurisdiction of the Court;
d. has been substantially diminished in value; or
e. has been commingled with other property which cannot be subdivided without difficulty.

it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other

property of the defendant up to the value of the property described above. All pursuant to 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p).

Dated:

for

Daniel P. Bubar
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

for

Gustav W. Eyler
Director
Consumer Protection Branch, Civil Division
United States Department of Justice

EXHIBIT 4

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.**
v.	)	
	)	**Violations:**
TIMOTHY BAXTER	)	**21 U.S.C. §§ 331(a), 352(a), 333(a)(1)**
	)	

INFORMATION

The United States charges that:

DEFENDANT

1. At all times relevant to this Information, the defendant, TIMOTHY BAXTER, was a resident of Richmond, Virginia.

2. At all times relevant to this Information through on or about December 23, 2014, BAXTER was the Global Medical Director of Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), a Delaware corporation with offices in Richmond, Virginia, that conducted business in the Western District of Virginia and elsewhere. RBP was a subsidiary of Company A. As the Global Medical Director of RBP, BAXTER reported to the top executive of RBP.

3. On or about December 23, 2014, RBP was demerged from Company A. Following the demerger, RBP was renamed Indivior Inc. and became a subsidiary of Indivior PLC, a United Kingdom company with offices in Slough, England, and Richmond, Virginia, that conducted business in the Western District of Virginia and elsewhere. After on or about December 23, 2014, BAXTER was the Chief Medical Officer of Indivior PLC, until he left the company in May 2016.

4. Indivior Solutions, Inc., previously known as Reckitt Benckiser Pharmaceutical Solutions, Inc., is a wholly owned subsidiary of Indivior Inc. Indivior Solutions, Inc. is a Delaware corporation headquartered in Richmond, Virginia. At all times relevant to this Information,

BAXTER had responsibility for and authority over Indivior Solutions, Inc.'s medical affairs. This Information refers to RBP, Indivior Inc. and Indivior Solutions, Inc. collectively as "Indivior."

5. At all times relevant to this Information, Indivior was engaged in the pharmaceutical business throughout the United States, including in the Western District of Virginia. Indivior's business included marketing, promotion, field sales, managed-care sales, and field-medical functions for drugs containing buprenorphine, an opioid, under brand names including Suboxone and Subutex.

LEGAL BACKGROUND

6. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans is a drug. 21 U.S.C. § 321(g).

7. The FDCA prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug or the causing thereof. 21 U.S.C. § 331(a). Under 21 U.S.C. § 333(a)(1) and applicable case law, a responsible executive with authority to either prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce may be liable for a misdemeanor violation of 331(a).

8. The FDCA provides that a drug is misbranded if, among other things, its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a). "Labeling" includes "brochures, booklets . . . letters . . . exhibits [and] literature . . . descriptive of a drug" whether or not it physically accompanies the drug when distributed. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2). Considering whether labeling is misleading requires assessing "the extent to which

the labeling . . . fails to reveal facts" that are "material" in light of "representations made or suggested by statement, word, design, device, or any combination thereof." 21 U.S.C. § 321(n).

SUBOXONE PRODUCTS

9. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continue to take opioids under medical supervision to avoid or reduce withdrawal symptoms while they seek to recover. The only opioid medication approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take at home) was buprenorphine, an opioid partial agonist and Schedule III controlled substance under the Controlled Substances Act.

10. On or about October 8, 2002, Indivior received approval from the Food and Drug Administration ("FDA") for the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet ("Suboxone Tablet") and Subutex Sublingual Tablet ("Subutex Tablet"). Indivior had previously obtained orphan-drug designation for buprenorphine for the "treatment of opioid addiction in opioid users." Among other things, this designation meant that Suboxone and Subutex were potentially eligible for 7-years of orphan-drug exclusivity upon approval (which would prohibit FDA from approving any competing application for buprenorphine for the same indication for 7 years). After approving these drugs, FDA determined that they were eligible and granted them orphan-drug exclusivity.

11. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but it could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps.

12. Subutex Tablet was similar to Suboxone Tablet, but it did not include naloxone. It was intended for induction and certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps.

13. In 2007, as Suboxone Tablet and Subutex Tablet neared the end of their period of exclusivity, Indivior began developing a new buprenorphine-containing drug for use in opioid addiction/dependence treatment: Suboxone Sublingual Film ("Suboxone Film").

14. Like Suboxone Tablet, Suboxone Film was a combination of buprenorphine and naloxone, but because aspects of the film formulation were patented, it arguably had patent protection. Suboxone Film differed from Suboxone Tablet in that (among other things) it has a thin form; sticks to the tongue/mouth; dissolves more rapidly; has potentially greater relative bioavailability at certain doses (as stated in the FDA-approved label); is formulated to taste better; and is packaged in individually wrapped, child-resistant foil pouches.

15. In August 2010, Indivior received approval from the FDA to market Suboxone Film for use in the treatment of opioid addiction/dependence.

16. At times relevant to this Information, Indivior marketed Suboxone Film to physicians and healthcare programs throughout the United States, including the Western District of Virginia.

PEDIATRIC EXPOSURE RISK

17. Suboxone Tablet, Subutex Tablet, and Suboxone Film, like many other drugs, carry a risk to children who take them by accident, sometimes called "unintended pediatric exposure." This risk of unintended pediatric exposure is identified in the Important Safety Information in

Suboxone's FDA-approved labeling, on its package, and in a Medication Guide and Physician Brochure with instructions on safe storage of the drug.

18. Indivior executives, including BAXTER, received data from poison control centers on unintended pediatric exposure for all buprenorphine drugs. During 2012 and thereafter, Indivior contracted with the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS") to analyze the data for rates and trends. Indivior's Medical Affairs Manager was Indivior's primary point of contact with respect to RADARS' pediatric exposure analysis projects in 2012, and reported directly to BAXTER.

PROMOTION AND DISTRIBUTION OF SUBOXONE FILM TO MASSHEALTH WITH MISLEADING LABELING

19. At all times relevant to this Information, sales of Suboxone Tablet, Subutex Tablet, and Suboxone Film generated substantially all of Indivior's revenue. After Indivior received FDA approval in August 2010 to market Suboxone Film, the company actively promoted only Suboxone Film. Indivior used RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film.

20. Before in or around December 2012, Suboxone Film was not a preferred drug on the Massachusetts Medicaid program ("MassHealth") formulary and had restrictions on approval for reimbursement. MassHealth was the largest Medicaid program in the country by volume of addiction-treatment-drug business. Thus, Indivior placed high importance on persuading MassHealth to expand coverage of Suboxone Film.

21. BAXTER was familiar with the issue of unintended pediatric exposure, and Indivior's use of analyses of unintended pediatric exposure. He attended meetings at which Indivior personnel and others discussed potentially arguing that there was a negative safety issue with tablets, and that Suboxone Film offered superior safety, though at the time no studies on this

issue had been performed. He attended meetings at which Indivior personnel told FDA personnel that Indivior believed Suboxone Film potentially could provide a means of guarding against unintended pediatric exposure, due to its packaging, though no studies on this issue had yet been performed. He attended a working session in which he and other Indivior personnel discussed potentially highlighting the issue of unintended pediatric exposure to doctors, though no studies of whether Suboxone Film had any benefit related to unintended pediatric exposure had yet been performed. And he emailed fellow Indivior personnel, reporting that the FDA appeared to have denied Indivior the ability to make a promotional claim that Suboxone Film provided additional safety with regard to unintended pediatric exposure, noting (among other reasons) that no studies on the issue had yet been performed.

22. In June 2012, BAXTER approved Indivior's retention of RADARS for access to data from poison control centers for use in analyzing unintended pediatric exposure.

23. On or about September 28, 2012, BAXTER and other employees received an email from Indivior's Medical Affairs Manager. In the email, the Medical Affairs Manager stated that a MassHealth official had reached out "requesting a meeting with me in his offices." The Medical Affairs Manager noted, "I am very excited at this opportunity to share the pediatric data" from RADARS, but asked to attend the meeting alone because "the situation . . . is very delicate." "You can rest assured," the Medical Affairs Manager wrote, "that we will have a successful meeting and things will change in Massachusetts."

24. On or about October 9, 2012, Indivior's Medical Affairs Manager met with the MassHealth official and provided a RADARS analysis of unintended pediatric exposure data from poison control centers nationwide. Following the meeting, the Medical Affairs Manager emailed a report of the meeting to BAXTER and others, stating that the MassHealth official was "very

responsive to the pediatric data," and adding, "[b]ecause RADARS can analyze exposure data to the 3-digit zip code in the US, my next step is that I have asked [RADARS] to do an immediate analysis of the rates of unintended pediatric exposure to buprenorphine tablets in Massachusetts as the utilization of tablets is high there and I expect that the rates of exposure follow suit. I am going to follow up with a telephone meeting with [the MassHealth official] to share this information." The Medical Affairs Manager then asked RADARS for an analysis of unintended pediatric exposure data for Massachusetts only, *i.e.*, a Massachusetts-specific analysis, to provide to the MassHealth official.

25. The next day, on or about October 10, 2012, RADARS provided the Medical Affairs Manager with the Massachusetts-specific analysis. It showed the rates of unintended pediatric exposure in Massachusetts for three categories of drugs: Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets (sometimes called "mono tablets"). The analysis showed that, in Massachusetts, there were 3.3 exposures per 10,000 unique recipients for Suboxone Tablets, 2.7 exposures per 10,000 unique recipients for Suboxone Film, and 1.8 exposures per 10,000 unique recipients for buprenorphine-only tablets. These data showed that buprenorphine-only tablets—which are packaged in bottles with child-resistant caps, in the same manner as Suboxone Tablet and many other drugs—had the lowest rate of unintended pediatric exposure among the three categories in Massachusetts.

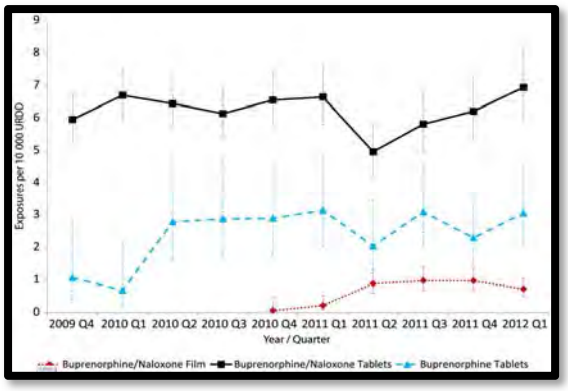
26. Upon receiving the analysis, the Medical Affairs Manager emailed RADARS, copying BAXTER, asking if she could "just add the mono and combo tablets to see the difference from film?" BAXTER responded, to the Medical Affairs Manager only, with the observation that the data RADARS sent "actually appear[ed] to make mono tablets look best or am I mi[s]-

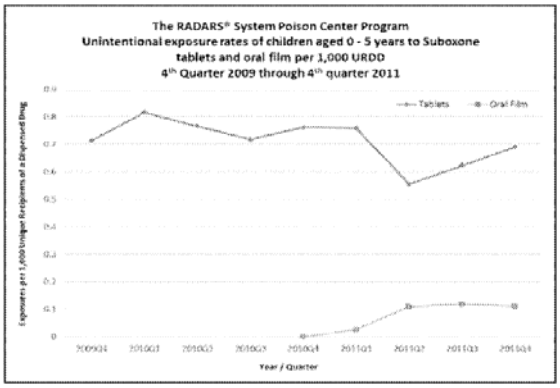
reading?" RADARS replied-all, indicating that it would obtain additional calculations and data that would be needed.

27. On or about October 16, 2012, the Medical Affairs Manager sent the MassHealth official an email containing false and misleading statements. The email contained a calculation of the unintended pediatric exposure data for Massachusetts that added the two tablet rates together when, in fact, adding the two tablet rates together would not provide an accurate calculation. Further, the Medical Affairs Manager indicated to the MassHealth official that she had received the calculations from RADARS when, in fact, she had not received them from RADARS, but had done the calculations herself. The Medical Affairs Manager stated to the MassHealth official in the email, and her calculations appeared to show, that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts when, in fact, buprenorphine-only tablets like Subutex Tablet had the lowest rate in Massachusetts, according to the RADARS data – a fact on which BAXTER had previously remarked. The Medical Affairs Manager then forwarded her email to BAXTER, stating that she sent it to the MassHealth official to "help us get some movement in Mass." BAXTER did not respond to this email.

28. On or about November 19, 2012, responding to a follow-up question about her false and misleading email referenced in the preceding paragraph, the Medical Affairs Manager sent the MassHealth official an email containing a chart with information from an Indivior promotional brochure (see image on right below) that referenced pediatric exposure data comparing the two products that contained both buprenorphine and naloxone, indicating that Suboxone Film had a substantially lower rate of pediatric exposure than Suboxone Tablets. The chart did not include a third line of data known to the Medical Affairs Manager that showed buprenorphine-only tablets (such as Subutex and generic equivalents) with a lower rate of pediatric exposure than Suboxone

Tablets, and with less of a difference in the rate of pediatric exposure than Suboxone Film (see image on left below). Shared in light of the Medical Affairs Manager's prior false and misleading email about unintended pediatric exposure rates in Massachusetts, the chart without the third line of data failed to reveal facts material to MassHealth prior to its updated formulary decision. By not including the data related to buprenorphine-only tablets, the Medical Affairs Manager reinforced her false and misleading claim that Massachusetts-specific data showed Suboxone Film as having the lowest rate of unintended pediatric exposure in the state. BAXTER was not copied on this email; however, around the same time, another Indivior employee emailed BAXTER, stating, "I couldn't help but notice that the chart did not show the [buprenorphine-only tablets] line. Does that mean we can also show the graph without [that] line? That would make such a huge difference!" BAXTER responded, "That chart is now published so nock [sic] yourself out!"





29. Subsequently, the Medical Affairs Manager received additional unintended-pediatric-exposure data showing that Suboxone Film did not have the lowest rate of unintended pediatric exposure in Massachusetts, for one quarter of 2012, but she did not provide the data to MassHealth. The Medical Affairs Manager later told other Indivior employees that her rationale for withholding the additional data from MassHealth was, "don't ask, don't tell."

30. In or about December 2012, MassHealth issued a press release announcing that it would "provide access to the unit-dosed film formulation to those members prescribed Suboxone

.

who live in households with children less than six years of age," citing to Indivior's nationwide pediatric exposure-rate data.

31. Indivior failed to correct the false and misleading statements made to MassHealth about unintended pediatric exposure in Massachusetts until December 2015, approximately two years after the government's investigation had begun. BAXTER approved sending a correction letter to MassHealth at that time.

32. BAXTER, as a responsible Indivior executive, failed to prevent and promptly correct the distribution of the false and misleading unintended pediatric exposure data and marketing claims to MassHealth.

COUNT ONE
Introduction of Misbranded Drugs in Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), 352(a)

33. Therefore on dates set forth in this Information, in the Western District of Virginia and elsewhere, the defendant,

TIMOTHY BAXTER,

a responsible Indivior executive, caused the introduction and delivery for introduction into interstate commerce of Suboxone Film, a drug that was misbranded in that the drug's labeling was false and misleading. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(a).

Dated: August 29, 2020

for Randy Ramseyer
Daniel P. Bubar
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

for Randy Ramseyer
Gustav W. Eyler
Director
Consumer Protection Branch, Civil Division
United States Department of Justice

EXHIBIT 5

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20CR00027
v.	)	
	)	**Violations:**
INDIVIOR SOLUTIONS, INC.	)	**18 U.S.C. § 1035**
	)	

CLERK'S OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
FILED

JUL 24 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

INFORMATION

COUNT ONE
False Statements Relating to Health Care Matters
18 U.S.C. § 1035

The Attorney for the United States[1] charges that:

DEFENDANT

1. INDIVIOR SOLUTIONS, INC. (hereinafter "INDIVIOR SOLUTIONS") is a wholly owned subsidiary of Indivior Inc., which was previously known as Reckitt Benckiser Pharmaceuticals Inc. ("RBP"). INDIVIOR SOLUTIONS was a division of RBP until it became a subsidiary corporation in September 2013. INDIVIOR SOLUTIONS is a Delaware corporation headquartered in Richmond, Virginia.

2. At times relevant to this Information, INDIVIOR SOLUTIONS was engaged in the pharmaceutical business throughout the United States, including in the Western District of Virginia. INDIVIOR SOLUTIONS' business included marketing, promotion, field sales, managed-care sales, and field-medical functions for drugs containing buprenorphine, an opioid, under brand names including Suboxone and Subutex.

[1] Authority conferred by 28 U.S.C. § 515.

3. Until December 2014, RBP and INDIVIOR SOLUTIONS were subsidiaries of Company A.

HEALTH CARE BENEFIT PROGRAMS

4. Medicaid is a health care benefit program under Title 18, United States Code, Section 24(b) that was administered by agencies of the various states to provide health care benefits and services to those who qualified. Medicaid is funded jointly by the states and by CMS and paid for certain prescription drugs for Medicaid beneficiaries.

5. MassHealth is the name of the Commonwealth of Massachusetts Medicaid program.

SUBOXONE TABLET AND SUBUTEX TABLET

6. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continued taking opioids under medical supervision to avoid or reduce withdrawal symptoms while they sought to recover. The only opioid approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take at home) was buprenorphine, a Schedule III controlled substance under the Controlled Substances Act.

7. On or about October 8, 2002, RBP received approval from the Food and Drug Administration ("FDA") for the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet ("Suboxone Tablet") and Subutex Sublingual Tablet ("Subutex Tablet"). The FDA designated both as orphan drugs, meaning the FDA committed not to approve any competitor drug for seven years (the "exclusivity period").

8. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but it could precipitate withdrawal if the drug were taken in other ways (*e.g.*, injected). Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps.

9. Subutex Tablet was similar to Suboxone Tablet, but it did not include naloxone. It was intended for induction and certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps.

SUBOXONE FILM

10. In 2007, as Suboxone Tablet and Subutex Tablet neared the end of their period of exclusivity, RBP began developing a new buprenorphine-containing drug for use in opioid addiction/dependence treatment: Suboxone Sublingual Film ("Suboxone Film").

11. Like Suboxone Tablet, Suboxone Film was a combination of buprenorphine and naloxone, but because aspects of the film formulation were patented, it arguably had patent protection.

12. Suboxone Film differed from Suboxone Tablet in that (among other things) it has a thin form; sticks to the tongue/mouth; dissolves more rapidly; has potentially greater relative bioavailability at certain doses (as stated in the FDA-approved label); is formulated to taste better; and is packaged in individually wrapped, child-resistant foil pouches.

13. In August 2010, RBP received approval from the FDA to market Suboxone Film for use in the treatment of opioid addiction/dependence.

14. At times relevant to this Information, INDIVIOR SOLUTIONS marketed Suboxone Film to physicians and healthcare programs throughout the United States, including the Western District of Virginia

PEDIATRIC EXPOSURE RISK

15. Suboxone Tablet, Subutex Tablet, and Suboxone Film, like many other drugs, carry a risk to children who take them by accident, sometimes called "unintended pediatric exposure." This risk of unintended pediatric exposure is identified in the Important Safety Information in Suboxone's FDA-approved labeling, on its package, and in a Medication Guide and Physician Brochure with instructions on safe storage of the drug.

16. INDIVIOR SOLUTIONS and others received data from poison control centers on unintended pediatric exposure for all buprenorphine drugs. During 2012 and thereafter, the data were analyzed by the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS") for rates and trends.

17. INDIVIOR SOLUTIONS used RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film. Specifically, INDIVIOR SOLUTIONS used RADARS analyses to assert that Suboxone Film provided greater protection against unintended pediatric exposure than other, similar drugs.

MATERIALLY FALSE STATEMENTS TO MASSHEALTH OFFICIALS

18. Before in or around December 2012, Suboxone Film was not a preferred drug on the MassHealth formulary and had restrictions on approval for reimbursement. To increase sales of Suboxone Film, INDIVIOR SOLUTIONS employees and agents sought to persuade MassHealth that Suboxone Film had safety benefits compared to other, similar drugs, in an effort to make Suboxone Film a preferred drug on the MassHealth formulary and boost profits.

19. On or about May 17, 2011, a purported physician, acting at the behest of INDIVIOR SOLUTIONS State Government Affairs employees submitted an Op-Ed Letter to The Boston Globe, The Boston Herald, and The Patriot Ledger, stating that Suboxone Film was "preventing diversion, recidivism, and the accidental death of inquisitive children," and by declining to provide Medicaid coverage of Suboxone Film, MassHealth officials were "engaging in 21st century biological warfare, no different than giving small pox infected blankets to the Indians."

20. On or about June 23, 2011, the same purported physician, again acting at the behest of INDIVIOR SOLUTIONS State Government Affairs employees, sent an unsubstantiated email to MassHealth officials stating, "there is less opportunity for diversion with" Suboxone Film, "there is less chance that a curious child will ingest the film," and "the inaction by the policy makers of MassHealth can be seen just as Strom Thurmond's filibuster in opposition of the Civil Rights Act of 1957." The purported physician subsequently emailed the INDIVIOR SOLUTIONS State Government Affairs employees, seeking a $30,000 donation to his foundation and a Harley-Davidson Road

King motorcycle as payment. The INDIVIOR SOLUTIONS State Government Affairs employees declined to make such payments.

21. On or about October 9, 2012, INDIVIOR SOLUTIONS Medical Affairs Manager met with a MassHealth official, and provided a RADARS analysis of unintended pediatric exposure data from poison control centers nationwide. After the meeting, the INDIVIOR SOLUTIONS Medical Affairs Manager asked RADARS for an analysis of unintended pediatric exposure data for Massachusetts only, *i.e.*, a Massachusetts-specific analysis, to provide to the MassHealth official.

22. The next day, on or about October 10, 2012, RADARS provided the INDIVIOR SOLUTIONS Medical Affairs Manager with the Massachusetts-specific analysis. It stated the rates of unintended pediatric exposure in Massachusetts for three categories of drugs: Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets such as Subutex Tablet (sometimes called "mono tablets"). It stated that in Massachusetts there were 1.8 exposures per 10,000 units for buprenorphine-only tablets such as Subutex Tablet, 3.3 exposures per 10,000 units for Suboxone Tablets, and 2.7 exposures per 10,000 units for Suboxone Film. These data showed that buprenorphine-only tablets like Subutex Tablet—which are packaged in bottles with child-resistant caps, in the same manner as Suboxone Tablet and many other drugs—had the lowest rate of unintended pediatric exposure among the three categories in Massachusetts.

23. Upon receiving the analysis, the INDIVIOR SOLUTIONS Medical Affairs Manager asked RADARS (copying RBP's Global Medical Director) if she could "just add

the mono and combination tablets to see the difference from film." However, adding the rates together would not provide an accurate calculation.

24. On or about October 16, 2012, the INDIVIOR SOLUTIONS Medical Affairs Manager sent the MassHealth official an email containing false and misleading statements. The email contained a calculation of the unintended pediatric exposure data for Massachusetts that in fact added the two tablet rates together. Further, the INDIVIOR SOLUTIONS Medical Affairs Manager indicated to the MassHealth official that she had received the calculations from RADARS, when in fact, she had not received them from RADARS, but had done them herself. The INDIVIOR SOLUTIONS Medical Affairs Manager stated to the MassHealth official, and her calculations appeared to show, that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts, when in fact, buprenorphine-only tablets like Subutex Tablet had the lowest rate in Massachusetts. The INDIVIOR SOLUTIONS Medical Affairs Manager then forwarded this email to RBP's Global Medical Director, stating that she sent it to "help us get some movement in Mass."

25. Subsequently, the INDIVIOR SOLUTIONS Medical Affairs Manager received additional unintended pediatric exposure data that did not show that Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts, and did not provide it to MassHealth. At an RBP corporate conference, the INDIVIOR SOLUTIONS Medical Affairs Manager told other INDIVIOR SOLUTIONS employees that her rationale for withholding the additional data from MassHealth was, "don't ask, don't tell."

26. In or about December 2012, MassHealth issued a press release announcing that it would "provide access to the unit-dosed film formulation to those members prescribed Suboxone who live in households with children less than six years of age," and citing to INDIVIOR SOLUTIONS' nationwide pediatric exposure rate data.

27. INDIVIOR SOLUTIONS failed to correct its inaccurate, false, and misleading statement made to MassHealth about unintended pediatric exposure in Massachusetts until December 2015, after the government had seized documents related to the false statements in a search warrant executed at RBP's Richmond, Virginia, headquarters. During an intervening period between December 2012 and December 2015, MassHealth reimbursed at least a portion of the cost for Suboxone Film prescriptions written for certain of its beneficiaries, all to the benefit of INDIVIOR SOLUTIONS.

28. Therefore on dates set forth in this Information, in the Western District of Virginia and elsewhere, the defendant

INDIVIOR SOLUTIONS, INC.

knowingly and willfully made materially false statements to MassHealth in connection with the delivery of and payment for health care benefits, items, and services, all in violation of Title 18, United States Code, Section 1035.

NOTICE OF FORFEITURE

1. Upon conviction of the offense alleged in this Information, INDIVIOR SOLUTIONS shall forfeit to the United States property that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of knowingly and

willfully making false statements relating to health care matters in violation of 18 U.S.C. § 1035, pursuant to 18 U.S.C. § 982(a)(7).

2. The property to be forfeited to the United States is a forfeiture money judgment of up to $289,000,000 (Two Hundred Eighty-Nine Million Dollars) pursuant to 18 U.S.C. § 982(a)(7) and 28 U.S.C. § 2461(c), in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

3. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;
b. has been transferred or sold to, or deposited with a third person;
c. has been placed beyond the jurisdiction of the Court;
d. has been substantially diminished in value; or
e. has been commingled with other property which cannot be subdivided without difficulty.

it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above-described forfeitable property, pursuant to 21 U.S.C. § 853(p).

Dated:

_____
Daniel P. Bubar
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

_____
Gustav W. Eyler
Director
Consumer Protection Branch
United States Department of Justice

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Dated:

Daniel P. Bubar
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

Gustav W. Eyler
Director
Consumer Protection Branch
United States Department of Justice

Seen and Agreed to:

Indivior Solutions, Inc.

BY: _____ 7/24/20
Javier Rodriguez — DATE
Authorized Corporate Representative for Indivior Solutions, Inc.

_____ 7/24/20
James R. Wooley — DATE
Counsel for Indivior Solutions, Inc.

_____ 7/24/20
Thomas W. Beimers — DATE
Counsel for Indivior Solutions, Inc.